



**IMPROVING OFFLOADING
FOR THE FOOT IN DIABETES:
USE OF TOTAL CONTACT
CASTING IN PRACTICE**

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Foreword

There are approximately 18.6 million people across the globe that are affected by a diabetic foot ulcer (DFU) every year (Armstrong et al, 2023), underlining the significant burden placed on healthcare systems. The scale of the problem in the UK is amplified by the growing number of people with diabetes in the population (Diabetes UK, 2023). There are estimated to be more than 5 million people in the UK living with diabetes: over 4.3 million appear in Diabetes UK data as having diabetes, while a further 850,000 could be living in the UK with diabetes who are yet to have been diagnosed (Diabetes UK, 2023). DFUs have a major detrimental, long-term impact on morbidity and mortality rates, and an individual's quality of life (Brownrigg et al, 2012).

In the UK, studies have shown that there are around 450,000 people with diabetes that develop a DFU at some point in their lives, which equates to approximately 10% of those diagnosed with diabetes (NHS North West Coast Strategic Clinical Network, 2017). In addition, some 7,000 diabetes-related amputations are performed every year in the UK. Time is of the essence when it comes to avoiding amputation in these individuals with DFUs, given that an estimated 17% of this patient cohort will have at least one amputation within 12 months from initial presentation with a foot ulcer (Guest et al, 2018).

The seriousness of the development of a DFU is starkly expressed by Armstrong et al (2007), explaining that individuals with lower-extremity complications of diabetes have 5-year mortality rates similar to or worse than most common types of cancer. From a UK perspective, there could be as many as 200,000 individuals with diabetes and foot ulcers that may not be alive in 5 years' time and that over 5,500 patients with diabetes-related amputations each year have less than 5 years to live.

DFUs come with a considerable cost. The mean cost of the management of a DFU is £7,800, ranging from £2,140 to £8,800 per healed and unhealed DFU, respectively, and £16,900 per amputated wound (Guest et al, 2018). This translates to an annual NHS cost attributable to managing these DFUs standing at between £524.6 million and £728.0 million (Guest et al, 2018).

It is acknowledged that the prevention and treatment of DFU requires multidisciplinary management, and integral to this is the use of offloading. International guidance stresses the importance of offloading for people with diabetes and complex wounds: "Offloading mechanical tissue stress is arguably the most important of multiple interventions needed to heal diabetes related foot ulcers" (Bus et al, 2023).

For people with diabetes and a neuropathic plantar forefoot or midfoot ulcer, the International Working Group on the Diabetic Foot (IWGDF) recommends that a non-removable knee-high offloading device be utilised (Bus et al, 2023). Described as the 'gold-standard' non-removable device, the total contact cast is used to redistribute pressure on the foot and can be used to treat DFUs. Despite the fact total contact casting (TCC) is the gold standard, the evidence points to the fact that it is not widely used. A range of reasons have been emphasised as to why this is the case, including a requirement for training and poor acceptance levels from patients (Boulton et al, 2018).

The IWGDF guidelines recommend use of a total contact cast or knee-high walker for individuals with diabetes and a neuropathic plantar forefoot or midfoot, based upon "local resources and the person's individual factors and acceptability" (Bus et al, 2023). Despite the widespread recognition that total

contact casts are the optimal device to take weight off of the foot in patients with DFUs, they are poorly utilised: it is estimated that just 5% of patients receive a load redistribution device (Guest et al, 2018).

Of 895 diabetic foot centres in the US, just 1.7% used total contact casts for the majority of their DFU treatment (Wu et al, 2008), while the situation has been found to be less than ideal; the Eurodiale study examined 14 centres situated in 10 European nations and the take up of TCC was found to be 18% (Prompers et al, 2008).

To address this key issue directly, as well as a number of others, a group of experts convened for a round table meeting in London to develop this consensus document, focusing on the effective and appropriate use of TCC.

This consensus document aims to aid clinicians working with DFUs to:

- Identify when TCC should be used and with which patient groups, highlighting red flags for consideration
- Use standardised guides and pathways to support appropriate use of TCC (i.e. WiFi)
- Identify what level of education is required for staff and how this should be provided
- Look at ways to improve patient engagement, and the tools that are required to support this.

Resources, technical skill and availability of therapeutic load redistribution devices vary across the UK. The guidance in this consensus document is designed to equip clinicians to deal confidently with using TCC in practice. The overall aim is to enable more patients to receive gold-standard treatment, improving outcomes for patients and their quality of life.

This document is intended to be a continuation of the important work expressed in the Redefining and Demystifying Offloading for Diabetes Foot Care consensus document (Munro et al, 2021) and it is recommended reading for any individual seeking to gain expert guidance on the role of offloading in the care of the foot in diabetes.

Jacqui Fletcher, Chair

Definitions and terminology.

- 'Offloading' in diabetic foot management is a term generally understood as relieving pressure from an ulcerated area; in truth, this term should more correctly be used to describe the reduction, redistribution or removal of detrimental forces applied to the foot (Baker and Osman, 2016)
- There was some debate among the expert group regarding the appropriate use of the term 'offloading'. For the purposes of this document, the word 'offloading' is used to describe "ways to support the healing of foot ulcers in people with diabetes"; however, "the term may not provide a full understanding of the mechanics of therapeutic devices (Munro et al, 2021)"
- The terms 'load redistribution', 'load sharing' and 'axial offloading' may better convey the mechanics of therapeutic devices that clinicians have at their disposal (Munro et al, 2021)
- With most offloading techniques, the pressure being applied to the ulcer is reduced by redistribution. It is not fully removed.

The importance of offloading

The soft tissues of the foot are subject to four central types of force, whether at rest or during activity:

- Shear: when a material is moving in two or more directions at the same time due to single or multiple loads [Figure 1a]
- Compressive: when a material is squashed or squeezed between two or more opposing loads [Figure 1b]
- Frictional: when a force moves over the surface of a material while in contact with it, creating a 'drag' across the material's surfaces [Figure 1c]
- Tensile/strain: when a material is stretched by two or more opposing forces [Figure 1d].

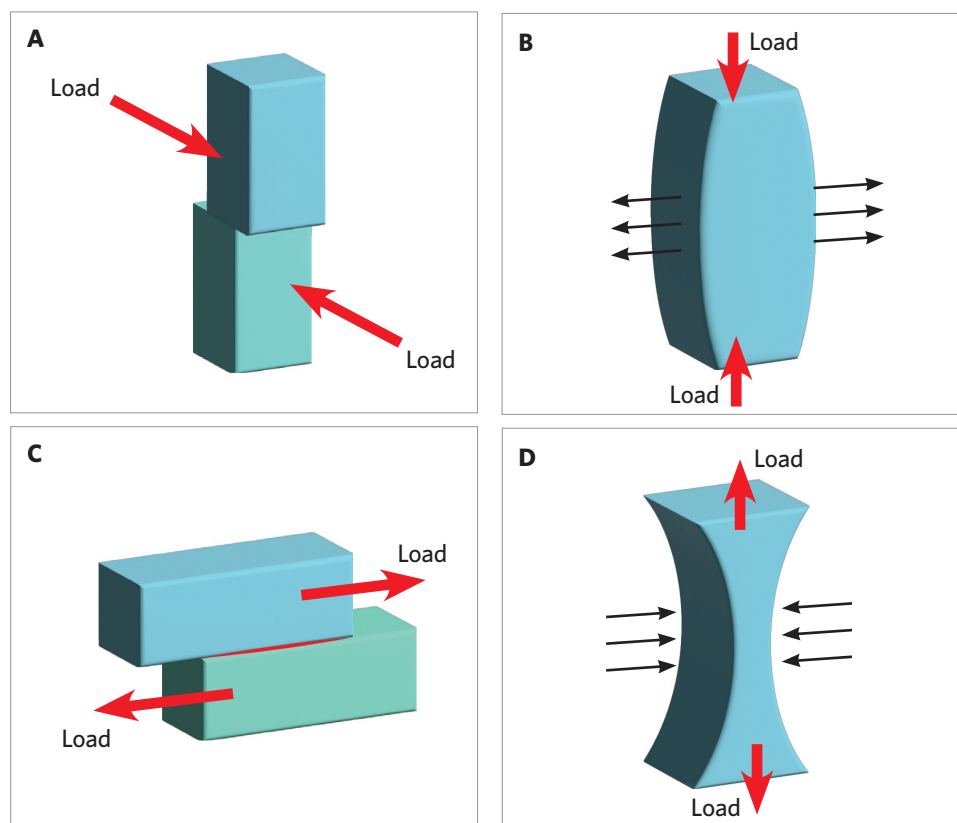


Figure 1. Types of force: (a) shear, (b) compression, (c) frictional, and (d) tensile force/strain (Baker and Osman, 2016).

The more vigorous the activity, the greater the magnitude of the applied forces. The fact that the soft tissues are protected from increased demands by a neural feedback mechanism leads the body to initiate slight movements to self offload and reload the specific areas subject to undue force. However, if these forces cannot be accommodated owing to previous damage or glycation, then damage is likely to occur (Baker and Osman, 2016).

The importance of offloading

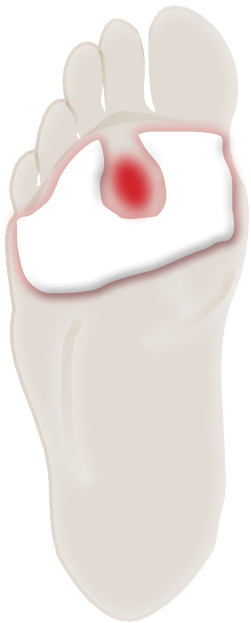


Figure 2. 'Doughnut' of felt.

Other considerations for the clinician, aside from recognising the detrimental forces applied to the foot, include:

- Magnitude: the size of the applied forces
- Direction: which way the forces are entering and exiting
- Velocity: the speed at which forces are applied and dissipated
- Duration: the amount of time any given force is in contact with the foot (Baker and Osman, 2016).

Elevated plantar pressure is a causative factor in the development of many plantar ulcers in individuals with diabetes, according to numerous retrospective and prospective studies (Cavanagh and Bus, 2010). Ulceration is often a precursor of lower-extremity amputation in those with diabetes. At the time of Cavanagh and Bus' study in 2010, there was insufficient evidence in the literature to support primary prevention of ulcers by offloading, although anecdotal evidence was in favour of such an intervention. Clinical opinion has now been replaced by widespread evidence in the literature that supports the use of offloading (NICE, 2019; IWGDF, 2023; National Wound Care Strategy, 2024).

There is a pressing need to reduce the causative factor in the ulcer's development (pressure damage) due to the fact that if the cause is not resolved then the ulcer is unlikely to heal. Examples of which would be:

- The individual is unable to move easily due to old age, having a spinal cord injury, chronic illness, etc
- Rapid weight loss which may result in the individual having less padding over bony areas
- Friction or rubbing of the skin on the heel due to ill-fitting shoes being worn
- Offloading in the management of the diabetes-related foot is "generally understood as relieving pressure from an ulcerated area" (Baker and Osman, 2016). Optimal offloading will stimulate the healing process and reduce injurious forces at an ulcerated site. A reduction in DFUs will result in a decrease in amputations, so offloading and amputation reduction go hand in glove. It is, however, crucial for the clinician to consider that whenever force is reduced or removed from one area, it relocates to another. As Baker and Osman (2016) state: "It would be disastrous to create a new lesion by overloading another area." Compressed felt does not deliver offloading, rather it increases pressure in other areas of the foot, as can be seen in **Figure 2**. It should be borne in mind that a dramatic edge at the periwound places additional stress on the tissues, which can cause a puckering effect or a new ulcer. It is important to remember that "the effectiveness of offloading [is] judged both by the relief of stress and by the patient's adherence to the treatment" (Cavanagh and Bus, 2010).

Who needs offloading?

Offloading is integral to healing neuropathic plantar foot ulcer in people with diabetes; indeed, Bus et al (2020) called it "arguably the most important" of multiple interventions, backed by a number of well-designed controlled studies (Najafi et al, 2016; Jeffcoate et al, 2017; Bus et al, 2018).

The guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2019 update; Bus et al, 2020) are unequivocal that a nonremovable knee-high offloading device should be the primary choice of offloading treatment.

When considering any offloading technique or device, Baker and Osman (2016) state that one very important physical law should be borne in mind: "The pressure under a curve is inversely

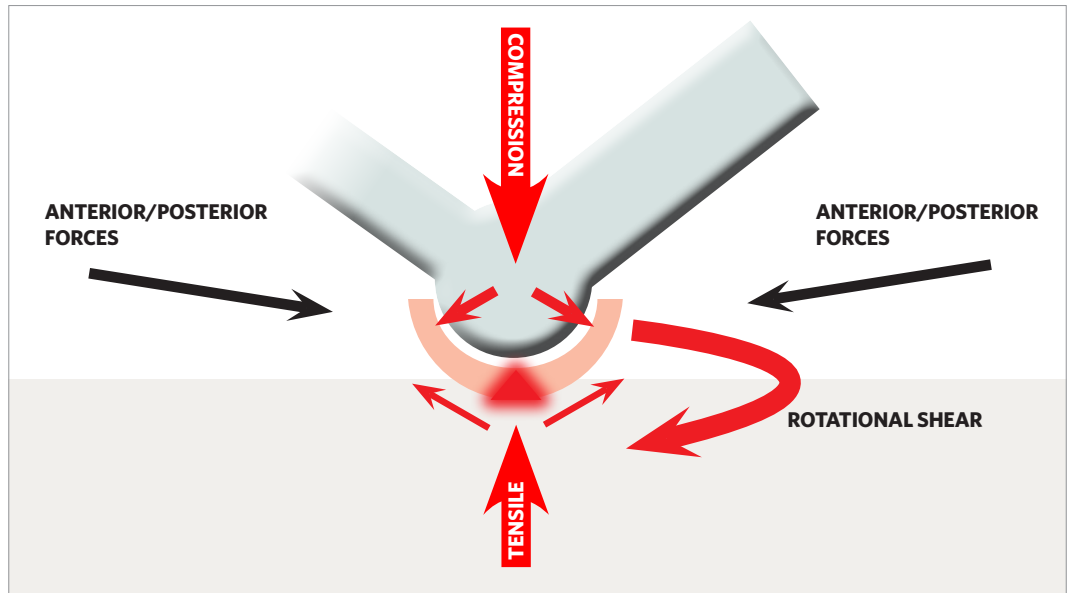


Figure 3. Some of the combined forces applied to an ulcer over a metatarsal head area. The triangle represents the ulcer.

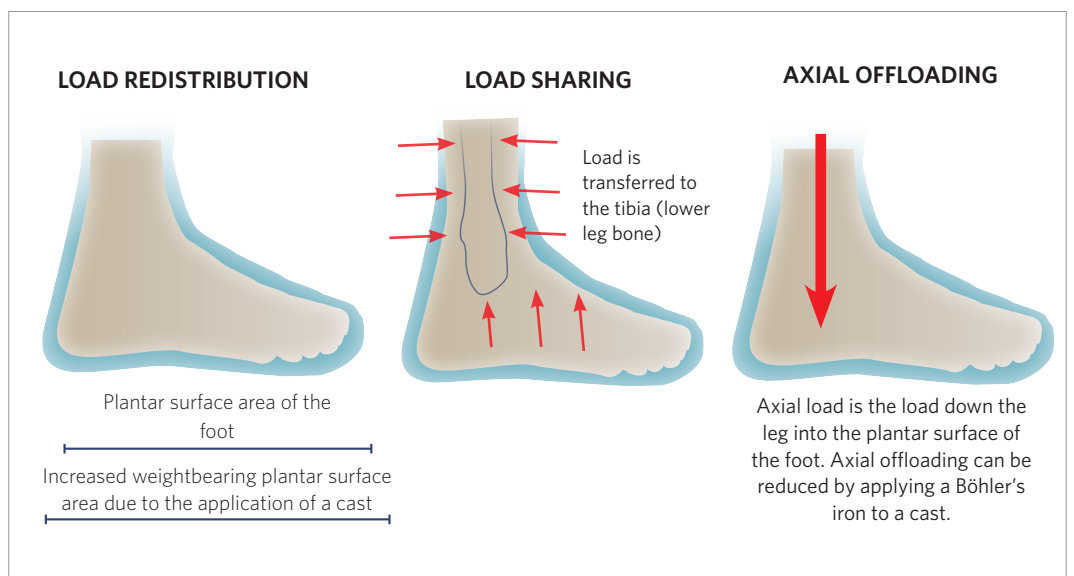


Figure 4. Load redistribution, load sharing and axial offloading of the foot. Blue shading indicates the effect of a therapeutic device (Munro et al, 2022).

proportional to the radius of that curve.” In essence, this means that “the smaller the curve, the greater the pressure/force beneath it”. The combined forces and their direction when applied to an ulcer over the metatarsal head area are illustrated in **Figure 3**.

The importance of offloading

Key points

- Application of a mechanical load to the skin, subcutaneous tissues and muscle during weightbearing activities can lead to increased pressure, damage and ulceration (Munro et al, 2022)
- IWGDF guidelines (2019 update) recommend that a non-removable knee-high offloading device should be the primary choice of offloading treatment.

In practice, this could be a tightly-fitting shoe worn by an individual with compromised arterial blood supply; the result is the development of a neuroischaemic ulcer. Another example would be that rubbing of the shoe on the foot goes unnoticed in an individual with a neuropathic foot, resulting in tissue damage taking longer to occur due to good blood flow (Baker and Osman, 2016).

How does TCC work?

Dr Paul Brand first adopted TCC for the treatment of diabetic foot ulcers in 1984 (Coleman et al, 1984) before modifying the technique, which involved cutting the amount of padding used to enable the cast to conform to the leg. It was Brand who introduced the theory of load redistribution, hypothesising that an increase in the weight bearing surface connected with TCC use resulted in a decrease in pressure area (Brand, 1991). This is supported by the fact that due to pressure being force divided by area, an increase in surface area over which the plantar force is applied will in turn reduce plantar pressure.

Due to TCC offering superior offloading compared to other options, such as the Aircast pneumatic walker, the DH pressure relief walker, and depth-inlay shoes, as outlined by Armstrong and Stacpoole-Shea (1999), it is concluded that it should be the 'go to' option for reducing pressure in the plantar heel. Armstrong et al (2014) found that total contact casts were the most effective offloading device when it came to peak pressure under metatarsal heads of DFU patients; mean pressure was 7 N/cm².

Shaw et al (1997) and Armstrong and Stacpoole-Shea (1999) reached the conclusion that decreased forefoot pressure is caused by the transmission of pressure to the cast wall or rearfoot. It can be assumed that the effectiveness of TCC can be directly attributed to the fact that it enables individuals to walk by uniformly distributing pressures over the entire plantar surface of the foot.

Both load redistribution theory and load sharing theory were postulated by Greenhagen and Wukich (2009) as reasons underpinning the effectiveness of TCC. A total contact casts mode of action rests on the principle of load transfer from forefoot to the rearfoot.

Meanwhile, load sharing was held up by Shaw et al (1997) as being the other mechanism critical to explaining how TCC works in offloading the foot. The success of load sharing is attributed by them for decreasing plantar pressure due to the proximal portion of the total contact cast bearing much of the load. The authors explained that the proximal cast wall or shank bore 30% of the load during ambulation. Similar findings were reported by Leibner et al (2006) with the cast bearing 36% of the weight bearing load in their study of 12 participants.

It is Kirby's theory of foot function that is taught in the UK on musculoskeletal (MSK) courses. The Subtalar Joint Axis Location and Rotational Equilibrium Theory of Foot Function centres on the spatial location of the subtalar joint axis in relation to the weightbearing structures of the plantar foot (Kirby, 2001). The theory lays out how the mechanical behaviour of the foot and lower extremity is affected by both externally generated forces (such as ground reaction force) and internally generated forces (such as ligamentous and tendon tensile forces and joint compression forces). Kirby's theory is currently most relevant in explaining how pressure is distributed in the foot and clarifying the results of prior research into the mechanical behaviour of the foot.

Total contact casting (TCC)

***Please note: Most clinicians in the UK use a polyester-based product and not fibreglass.**

Total contact casting (TCC)

The following definition of TCC comes from the 2023 update of the IWGDF guidelines: “Custom-made, well-moulded, minimally padded, knee-high non-removable fibreglass* or plaster cast that maintains total contact with the entire plantar surface and lower leg. The cast is often worn with an attachable sole that protects the cast and facilitates walking.” (It should be noted that a cast shoe must be used if a walking cast.)

These casts were traditionally made from plaster of Paris bandage, which was “intimately moulded to the lower leg and foot with padding only over the toes, malleoli and tibial crest” (Baker and Osman, 2016).

TCC gets its name from the way in which it intimately contours the foot. It is moulded by hand to the contours of the foot from the back of the heel through the arch region, the metatarsals and the toes. Pressure previously concentrated on the bony prominence of the foot becomes redistributed over the entire sole of the foot. TCC is designed to lock the heel and toes in place, with the result being that shear, stress and friction are all significantly reduced. The fragile wound bed and wound edges are, therefore, protected from shear and friction damage by the total contact cast.

A biomechanical assessment of the foot ankle joints is crucial to ensuring the correct application of a total contact cast. “The biomechanics of the diabetic foot is altered and maladaptive,” according to Paul Kim (Kim, 2013), with one of the main causative factors being peripheral neuropathy.

Clinicians should, therefore, pay close attention to flexibility and rigidity in range of motion by considering bony relationships, as well as the quality of connective tissue, particularly as this has an influence on range of motion.

Prevention of diabetic foot ulceration may be possible with early identification of the insensitive foot (the ‘at risk’ foot) and by protecting the foot from abnormal biomechanical loading. One of the ways of achieving this is by utilising TCC.

Although by no means form an exhaustive list, having an appreciation for the basic biomechanical deficits is key, including: hallux limitus, toe deformities, forefront alignment and midtarsal range of motion and talocrural joint limitation (Barr, 2015).

The evidence for TCC

TCC is the accepted gold standard for the offloading of forefoot and midfoot lesions and there is a body of evidence to support its use, healing between 72% and 100% of ulcers within 5–8 weeks (Mueller et al, 1989; Armstrong et al, 2001). The latter was a prospective clinical trial involving 63 patients with superficial non-infected, non-ischæmic diabetic plantar foot ulcers, which found that the healing rates in 89.5% of patients treated with TCC compared favourably with those treated with removable cast walkers (RCWs) and half shoe (65.0% and 58.3%, respectively).

Armstrong et al (2003) explained that the reason for total contact casts outperforming RCWs, despite both relieving pressures under the foot equally well, was that RCWs are frequently removed

Total contact casting (TCC)

Practice points

- Patients should be offered non-removable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers
- Alternatively, the patient should be offered an alternative offloading device until casting can be provided.

by the patient. The clinicians concluded that “control of this important aspect of care with less easily removable devices may increase the prevalence of healing”.

A systematic review conducted by members of the IWGDF in 2015 found that, although sufficient evidence existed in support of the use of non-removable offloading techniques to heal plantar forefoot ulcers, further high-quality studies were required “to confirm the promising effects of other offloading interventions, so to better inform clinicians and practitioners about effective treatment” (Bus et al, 2015).

One earlier high-quality study (Fife et al, 2014) utilising a large wound registry found that, at 1 year, the TCC-treated group reported significantly fewer amputations compared with the non-TCC-treated group (2.2% vs 5.2%; $p = .001$), as well as a significantly longer time to amputation (351 vs 317 days; $p = 2.8 \times 10^{-11}$). The authors concluded that “if TCC does help prevent or delay amputations among the patients commonly seen in wound centres, this finding would be an enormous cost-effectiveness argument for its use” (Fife et al, 2014).

The evidence base supporting the use of non-removable knee-high offloading devices (either a total contact cast or non-removable walker) as the first-choice offloading intervention for healing plantar neuropathic forefoot and midfoot ulcers is strong (Lazzarini et al, 2020).

The Guideline Development Group (GDG) has deemed the effectiveness of offloading devices as being dependent on patient tolerability and compliance of use. The GDG also noted that custom-made footwear was not a standardised practice within the UK (Internal Clinical Guidelines team, 2015).

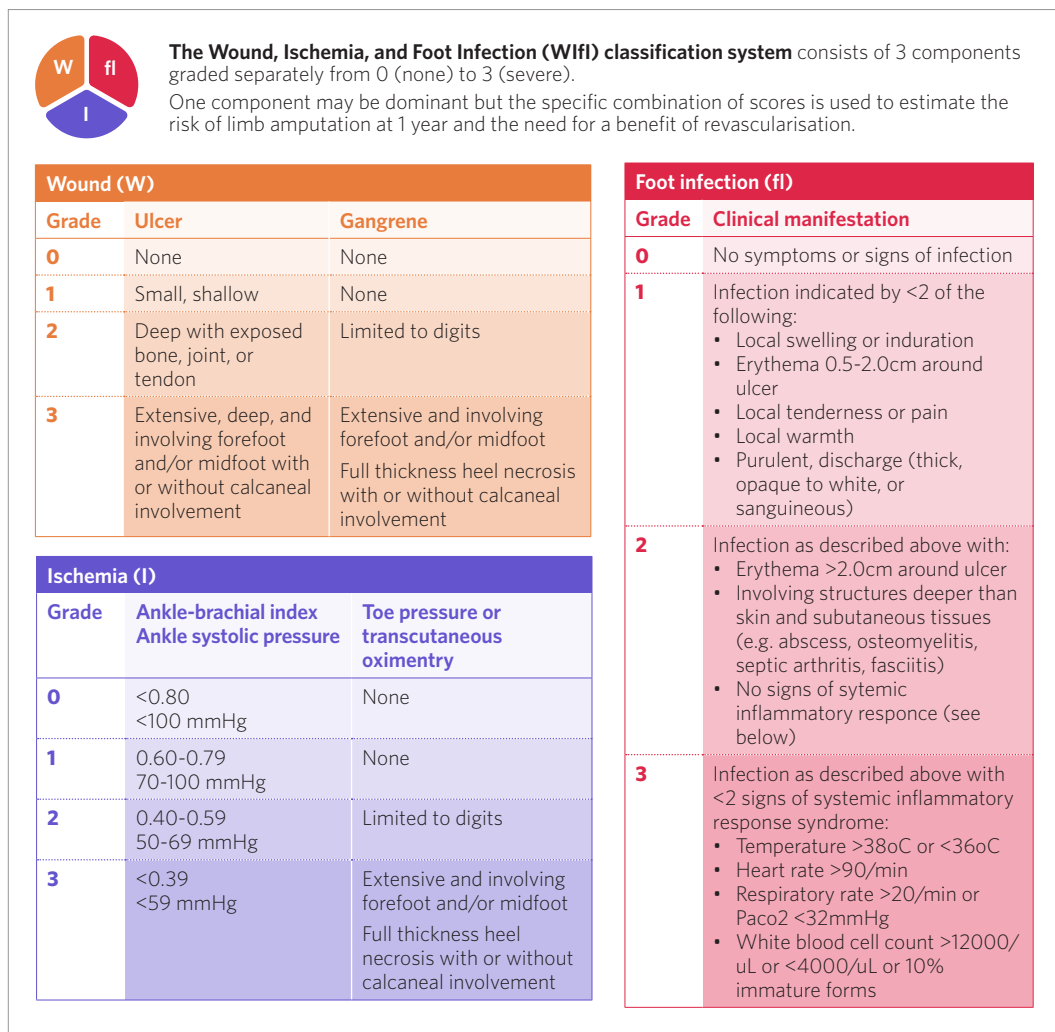
The IWGDF recommends a non-removable knee-high offloading device as the primary choice of offloading treatment those with diabetes and a neuropathic plantar forefoot or midfoot ulcer to promote healing, with TCC specifically cited to promote healing “based upon local resources and the person’s individual factors and acceptability” (IWGDF, 2023). Non-removable devices, such as TCC, are effective precisely because they cannot be removed, so they eradicate the problem of non-adherence in people with diabetes and DFU using it.

Underlining TCC effectiveness, another US study found that the use of TCC in offloading resulted in 88% healing, more than 32 points greater than the next most effective therapy (Greenhagen and Wukich, 2009). A widely recognised clinical observation is that no matter how well conformed to the foot, molded insoles and shoes do not reduce plantar loads as effectively as total contact casts.

Who is TCC an appropriate treatment for?

In terms of patient selection for TCC, it is recommended that all people at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure (NICE, 2019), and that patients should be offered non-removable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers; or else, the patient should be offered an alternative offloading device until casting can be provided.

Figure 5. Wifl classification system (Armstrong et al, 2023).



The IWGDF (2019) identified five high-quality meta-analyses of controlled trials focusing on the healing of foot ulcers with non-removable offloading that all pointed to the fact that non-removable offloading devices result in “significantly improved healing outcomes for neuropathic plantar forefoot ulcers when compared with removable devices (removable offloading devices or footwear)” (Lewis and Lipp, 2013; Morona et al, 2013; de Oliveira and Moore, 2015; Elraiyah et al, 2016; Ontario HQ, 2017).

The use of Wifl in patient selection for TCC

Use of the Wifl classification was recommended by the National Wound Care Strategy’s vascular guidelines (Gohil, 2022) to determine the overall degree of limb threat. Williams et al (2022) found that Wifl stages 1-4 corresponded better with time to healing, with stage 1 having the shortest time and stage 4 having the longest time. In addition, a “higher Wifl stage showed increased risk of foot/leg amputation at 1 year, whereas this did not change with SINBAD severity” (Williams et al, 2022).

Total contact casting (TCC)

Key points

- The WIfI (Wound, Ischemia, and foot Infection) Classification System is used to categorise these three major risk factors leading to amputation
- WIfI was found to be better at predicting outcomes than the SINBAD score in a cohort of patients with hard-to-heal DFUs in a specialist clinic (Williams et al, 2022).

Risk stratification is based on three key factors that impact the risk of amputation and clinical management: Wound, Ischemia and foot Infection (WIfI; Mills et al, 2014). The acronym WIfI can be used by clinicians as “short-hand for these factors, which can assist the health care team in describing patients’ overall limb threat status” (Boulton et al, 2018).

Originally created for chronic limb-threatening ischaemia (CLTI) in the diabetic patient, the three facets comprising the WIfI classification tool are graded for severity with 0 = none, 1 = mild, 2 = moderate and 3 = severe, be it for Wound, Ischemia or foot Infection.

The efficacy of the WIfI classification tool was underlined in a study at Leeds Teaching Hospitals NHS Trust that included 119 patients with 129 foot wounds designed to compare the SINBAD and WIfI classification systems in the risk stratification of DFUs (Williams et al, 2022). The authors found that WIfI was better at predicting outcomes than the SINBAD score in a cohort of patients with hard-to-heal DFUs in a specialist clinic, despite the SINBAD (Site, Ischaemia, Neuropathy, Bacterial infection and Depth) score currently being the most widely used classification in the UK.

Williams et al (2022) uncovered that WIfI stage 1-4 correlated better with time to healing, with stage 1 being found to have the shortest time and stage 4 having the longest time. The study showed that, the higher the WIfI stage, the increased risk of foot/leg amputation at 1 year; this did not change with SINBAD severity.

Given that the WIfI system may better quantify risk of amputation and also guide clinicians in terms of revascularisation, it will be used in the decision-making/visual tool for TCC in this document (see page 20).

It should be noted that if ischaemia is suspected, the patient should be referred for non-invasive vascular assessment before applying a non-removable cast, such as a total contact cast. This is equally true for untreated and unresolving infection. This is important as the emphasis needs to be moved from classification to good clinical assessment and practice.

Patient engagement and acceptability

Box 2. Maximising patient capacity and involvement (adapted from General Medical Council, 2016).

- Wherever possible, discuss treatment options in a time and place that helps the individual to understand and remember what you say
- Ask whether having a friend or relative with them might help them to remember the information, or otherwise help them to maintain their treatment
- Offer written, visual or audio information where possible if it will help
- Speak to the individual's relatives, friends or others in their healthcare team about how best to communicate with the individual and aid with engagement with treatment.

Patients have the right to be involved and informed about their own care: it is important for them to be aware they have the right to ask questions and make comments. The clinician should help to encourage an environment where the patient feels safe and supported, and able to speak up about their needs, preferences and concerns (WUWHS, 2020; see **Box 2**).

Successful offloading is a treatment that requires commitment from the patient, and they need to be fully aware of the benefits and challenges of this. Individualised, evidence-based care is key, as a 'one-size-fits-all' approach does not work. It is important to tailor care to the individual: their condition, their general health and their practical circumstances. However, consistency of care is also an important element — particularly when it comes to a recognised 'gold standard' treatment such as TCC. Balancing the patient's preferences with the need for efficient treatment is key.

Contraindications of TCC

- TCC is contraindicated in those with severe peripheral arterial disease, untreated osteomyelitis or infection (Udovichenko et al, 2013), as well as those with extensive necrosis. Total contact casts do not allow patients, carers or healthcare providers to assess the foot or wound on a daily basis. Therefore, for heavily exudating wounds necessitating daily dressing changes, a total contact cast may not be appropriate
- Additional contraindications include exposure of tendon, joint capsule or bone, severe cardiac problems, end-stage renal failure, iatrogenic lesion, infected ulceration, extensive necrosis and those with knee, hip and spine pains attributed to leg length discrepancy
- As with any treatment plan, it is essential to carefully consider patient engagement. Patients must be able to engage with the cast care instructions and attending regularly scheduled appointments for debridement and recasting. As such, the use of a total contact cast may not be deemed appropriate in cases where patients are not actively engaging in their treatment or are exhibiting signs of mental instability.

Risk-benefit and communication

A risk-benefit conversation is an important factor in aiding adherence to offloading devices. When a person walks into a consultation with a clinician and they have presented with a DFU, in an ideal world, they should not be leaving the room in the same footwear they came in wearing. One person's needs differ from the next's so their available options should be discussed with them, alongside the risks associated with each possible selection. Not every clinic can provide different footwear; however, if a patient presents with a neuropathic plantar ulcer, then offloading must be initiated in some form. Referral is crucial here, perhaps with a rapid step-wise approach to suitable offloading. For instance, it may be that the patient has a manual job and their livelihood is reliant on turning up to work each day as they are self-employed. It may be the case that TCC is not a viable option but the individual should be made aware of the risk of not using the gold-standard option.

That said, individuals with a DFU and deemed suitable for treatment with a total contact cast must be armed with the knowledge that the "efficiency of footwear in offloading and patient adherence correlates directly with ulcer healing rates and the duration to ulcer healing" (Shearman and Chong, 2023). It may well be that they respond positively to the old adage "short-term pain for long-term gain". The "pain" in this sense could be the negative perception of wearing a cast they

Key points

- Offloading is a balance between footwear acceptability to maximise compliance versus footwear effectiveness in ulcer healing (Shearman and Chong, 2023)
- Patient respect and empowerment should be considered of central importance.

cannot take off for cosmetic reasons or if wearing a TCC adversely affects their ability to work or drive. As Shearman explains: “Offloading is a balance between acceptability of the footwear to maximise compliance versus the effectiveness of that footwear in ulcer healing” (Shearman and Chong, 2023).

Baker and Osman (2016) highlight that TCC is “the accepted gold standard for the offloading of mid- and forefoot lesions”. Just as a cast is the accepted standard for a fractured foot/ankle, TCC is the suggested treatment for forefoot/midfoot lesion and anything else is a compromise that will delay healing.

Family and carer involvement should be considered as a part of this approach, with all stakeholders as involved and informed as possible (WUWHS, 2020). Communication with the patient and their family/carers is key. Patient respect and empowerment should be considered of utmost importance. Treatment is likely to be most effective if the individual feels involved in their own care, informed of the rationale behind it, and given a clear plan to follow (WUWHS, 2020).

Psychological impact

The psychological impact on patients living with a wound should never be underestimated and differs from person to person. Ousey and Edward (2014) state that “adverse psychological effects frequently occur when there are permanent changes in the body’s structure or function”.

In terms of DFUs specifically, a study involving 333 patients with diabetic peripheral neuropathy (Gonzalez et al, 2010) found that psychological factors significantly impact the development of a wound, independent of biological risk factors and foot self-care (HR 1.68, 95% CI 1.20-2.35). So-called ‘cast phobia’ or cast anxiety is a phenomenon that presents as an overwhelming tightness, excessive anxiety or basic intolerance by a patient to their cast. Typically presenting 1 day to 2 weeks after cast application, Ross et (2020) explain that “tampering with casts has been documented, prompting further research aimed at investigating the management of [cast anxiety] in claustrophobic patients”. Understanding the needs of individuals with cast anxiety is imperative and it may well be that a total contact cast is not a suitable treatment option for this cohort.

Overcoming the psychological impact of wearing a total contact cast

Tips to overcome the psychological impact of wearing a total contact cast:

- Involving patient champions: discussion with patient champions is recommended to help aid clinical decision-making
- Education and empowerment: provide education about the cast, its benefits, and the expected duration of wear. Discuss the healing process and the role of the cast in facilitating recovery: having a clear understanding can help alleviate anxiety and increase acceptance of the treatment
- Demonstrating ulcer improvement: showing photos pre- and post-casting will demonstrate improvement in healing and appearance, thus promoting a positive outlook
- Open communication: encourage communication and patient-centred care. Address concerns, answer questions and provide reassurance throughout the treatment process. By establishing trust and rapport, individuals feel supported and this can reduce feelings of isolation or uncertainty
- Encouraging independence: there will be activities the individual can still engage in while wearing the cast. Encourage this as a way to maintain as much independence as possible in daily activities, such as personal hygiene, mobility and participation in light exercise approved by healthcare professionals. This fosters a sense of control and normalcy
- Encouraging strong support networks: facilitate connections with support groups, online forums, or peers who have experienced similar situations. Sharing experience and receiving encouragement from others can provide emotional support and validation for individuals undergoing treatment requiring cast
- Providing psychological interventions: offer psychological support through counselling therapy, or relaxation techniques to help individuals manage stress, anxiety or depression related to wearing the cast. A growing number of multidisciplinary foot services have psychologists as part of their teams
- Provide reassurance: give the patient a demonstration cast to touch and feel. The lightweight aspect could be demonstrated, for instance
- Customisation and personalisation: offer options for personalising the cast. This may involve a choice of colour or design. Customising can help individuals feel a sense of ownership
- Monitor and follow-up: it is important to monitor the individual's psychological wellbeing and address any emerging concerns promptly, making adjustments as and when needed
- Provide written information to support the patient: this should include knowledge of who to contact if needed to urgently have the cast removed.

Practical concerns

Key points

- A study by Fife et al (2014) found that although 96.3% of reported DFUs were eligible for TCC, it was not used at all
- Some clinicians may favour removable walkers given they take less time to apply
- Although total contact casts were originally contraindicated in patients with ischaemia or infection, this has now been reversed.

A common scenario experienced by clinicians is that concern is expressed over transportation to and from the clinic, given that TCC restricts movement in the foot. Therefore, there needs to be a conversation with the patient, family and friends to allay fears over lack of independence and inability to perform certain tasks, such as driving, before TCC application.

Sometimes, just talking through certain things that may seem trivial can be a source of reassurance for the patient. When showering, clinicians can recommend numerous cast protectors to prevent the cast becoming wet, while the conundrum of protection for the contralateral leg while the patient sleeps can be solved by simply placing a pillow between their legs when they sleep. It has become clear that people with diabetes requiring amputations have been lacking proper offloading techniques. As Chadwick (2021) explains, guidelines for offloading are not always followed in practice. The technique is not widely used in clinical practice, possibly due to a lack of education, training and resources.

A study carried out by Fife et al (2014) found just 2.2% of the total 221,192 clinic visits saw the use of offloading reported, with TCC used in only 16% of the DFU visits that saw offloading used ($n = 781$). Alarming, a huge 96.3% of the patients with DFUs reported were eligible for TCC, yet it was not used in their treatment. Equally noteworthy was the fact that just 59 out of the 96 clinics studied used TCC as a treatment option.

Shearman and Chong (2023) expound that removable walkers take a fraction of the 60 minutes fitting time, which may go some way to explaining why TCC is used routinely for neuropathic ulceration in just 2% of US clinics, in addition to the knowledge that TCC requires skilled technicians in its application.

Non-removable walkers, such as total contact casts, were originally contraindicated in patients with ischaemia or infection — a situation that has now reversed given that the IWGDF deems TCC as the first-line treatment in patients with mild ischaemia or mild infection — which may also explain a reluctance to use TCC with this cohort.

The gap that exists in practice when TCC is the gold standard is, therefore, worrying given the amount of limbs and lives at stake. Fife et al (2014) have called for easier-to-apply and faster techniques being rolled out comprehensively to create a more competent and skilled workforce. However, concern was raised by the panel that TCC can be applied too quickly.

Other practical concerns include:

- Instability due to limb length alteration
- Instability due to loss of proprioception or muscle strength
- Weight of cast — be wary of muscle atrophy
- Loss of mobility and its impact
- Lower back pain and possible sciatic nerve pain
- Consider cardiac stress, especially in those with poor ejection fraction, cardiac myopathy, left ventricular hypertrophy, etc.

Cost-effectiveness of TCC

Key points

- In 2014-2015, the cost of health care for ulceration and amputation for individuals with diabetes was estimated between £837 million and £962 million — between 0.8% to 0.9% of the National Health Service (NHS) budget for England (Kerr et al, 2019)
- If the NHS reduces the prevalence of DFUs in England by one-third, the gross annual saving would be more than £250 million.

In 2014-2015, the cost of health care for ulceration and amputation for individuals with diabetes was estimated to stand between £837 million and £962 million (Kerr et al, 2019); this translates into between 0.8% to 0.9% of the National Health Service (NHS) budget for England. Diabetic foot care, therefore, accounts for a substantial proportion of healthcare expenditure in England — “more than the combined cost of breast, prostate and lung cancers” (Kerr et al, 2019).

With much of the expenditure relating to prolonged and severe ulceration (more than 90%), should the NHS reduce the prevalence of DFUs in England by one-third, the gross annual saving would be more than £250 million (Kerr et al, 2019).

Woo (2016) set out to explore the cost-effectiveness of an easy-to-apply TCC system for DFUs, challenging the assumption that cost is an often cited barrier for not adhering to an offloading device. The cost-effectiveness study took place between 2014 and 2016, with 15 patients reviewed — the final analysis was carried out on 11 of those patients, as two patients developed infection and two patients had issues with adherence.

TCC treatment costs ranged from C\$251.84 to C\$1236.08, with 10 out of the 11 patients achieving closure. This compared favourably with the cost of conventional treatment, which ranged from C\$1,090.95 to \$10,252.80. The total cost of treating the 11 patients with TCC resulted in huge savings of 75% when compared with conventional treatment. TCC could result in cost savings for the NHS because of the reduced amount of amputations performed, as well as the release of significant amounts of clinical time because the wounds heal and do not result in repeats clinical visits/appointments.

Patient expectations

Benefits and expectations for patients

Three key questions for clinicians regarding the use of TCC relate to the 'when', the 'what' and the 'how':

- When do we need to be aware of risk, be it re-ulceration or amputation?
- What can we do to minimise risk?
- How can we feel confident in the decisions taken?

The importance of attending foot screening should be stressed to the person with diabetes as a means to keep them engaged with the risks associated with their condition. Leese and Stang (2022) strongly advised that the clinician undertaking the screening procedure uses the SCI-Diabetes foot screening tool, which "allows the individual with diabetes to be informed of their risk immediately and counselled with verbal and written advice, and also allowing the HCP/worker to have immediate guidance as to the recommended action to direct appropriate care while automatically populating results into the annual Scottish Diabetes Survey".

The patient should be able to have a full and frank conversation with the clinician surrounding expectations of treatment and what using a total contact cast will involve. For example, patients will not be able to drive a manual car while in the cast and this obviously raises concerns about transportation to and from the clinic (Rodgers, 2015).

Increasing knowledge and awareness for clinicians

As far back as 1989, experts were warning of the importance of careful application, close follow-up and patient compliance with scheduled appointments in order to minimise complications (Mueller et al, 1989). Today, there still exists a fear that the wound could worsen or other wounds could occur in the individual with a DFU, which could prove catastrophic.

These barriers can be overcome "with minimal training, proactive planning and appropriate patient education" (Rodgers, 2015). It is important to bear in mind that different levels of skill and competency are required depending on application type. Furthermore, it is well established that the management of DFU is best practiced by a multidisciplinary team (Blanchette et al, 2020).

Application of a non-removable total contact cast, removable total contact cast and slipper cast/heel cup should only be undertaken by someone who has had the necessary training to be deemed competent in the underpinning knowledge and application skills aligned to any of the application options.

Higher education institutes have a responsibility to offer education that supports clinicians, to develop the knowledge and skills they need to be fit for practice, when treating patients with tissue viability-related problems (Ousey et al, 2011). Therefore, it is evident that clinicians may benefit from an accredited course or clinical modules on the management of DFU.

Modern TCC systems are customisable for most legs and easy to apply and remove, so it is incumbent on more senior staff to endeavour to extoll the virtues of TCC as the gold standard treatment for DFUs to more junior members of staff. An emphasis should be placed on explaining the increase in wound healing rates, decrease in the time to heal and cost savings made by using TCC over other methods of offloading.

Explaining risk to patients

In the UK, 7.1 million adults read at, or below, the level of an average 9-year-old (NHS Health Education England, 2022). Therefore, any information provided to patients to support their health literacy, education and understanding needs to be clear, simple, jargon-free and graphical/visual. More than 4 out of 10 adults in the UK struggle to understand health content available in the public sphere (National Institute for Health and Care Research, 2022). Indeed, the director of the Patient Information Forum, Sophie Randall, stated: “It is the duty of health information producers to be ‘health-literacy’ friendly in all they do. It is a crucial element of tackling health inequality and misinformation. This was demonstrated by the COVID-19 pandemic. Health information must be accessible to all (National Institute for Health and Care Research, 2022).”

Patient education could be used to emphasise the risks associated with taking off the total contact cast. These may take the form of QR codes on the device itself that link to advice in the form of a webpage, while videos and leaflets could also play a role.

The clinician should bear in mind that if a cast can be removed, it probably will be, and will only be worn when attending clinic appointments; armed with this knowledge, the importance of highlighting the risks associated with such a mindset to patients is clear.

For individuals with diabetes, foot screening is an opportune moment to address the ‘elephant in the room’, namely the increased risk of amputation that is associated with the condition. A risk-benefit conversation is recommended, revisiting the patient’s preference of offloading method and the downside of selecting anything less than a total contact cast if they are suitable for one.

There are a few disadvantages to TCC that could potentially prove to be detrimental to its uptake. See **Table 1** for more information on potential disadvantages of a total contact cast for the patient, and how these may be overcome in practice. It is crucial that the patient, their family and carers are educated about the intricacies of wearing a cast and the specific signs that may indicate whether or not there is a problem. It is, therefore, of significant importance that both verbal and written casts instructions are made available.

| | |
|--|--|
| The cast may rub and cause other wounds to develop on the patient’s foot or leg | Advise the patient how best to avoid activities that may aggravate the foot or leg |
| The patient may not be able to work while wearing the cast | Offer advice on how to find an alternative to affected elements of their daily routine; for example, it may be that a walker enables the individual to become more independent |
| The patient is unable to drive while wearing the cast | Talk through the options with the patient for appropriate alternatives; brief family and friends if they are in attendance |
| The patient may fear falling or report difficulties in managing daily activities | Prescribe a walker and a cast protector for use in the shower |
| Time of application | Train staff to become confident with application |
| Cast slippage can occur due to oedema reduction after applying a leg cast | Train staff to be on the lookout for this and to mitigate it as and when it occurs |
| Cast sores can occur | Advise patients and carers about the ‘danger signs’ — check daily for swelling, cast strikethrough, pain/soreness, bad odour, etc |

Decision-making tool for TCC

To aid with clinical decision-making, a visual tool was created for the use of TCC in practice [Figure 4]. This clinical treatment pathway seeks to be as seamless as possible. When a patient attends the multidisciplinary foot clinic with a neuropathic ulcer, the patient will be placed into a non-removable cast. The patient will then have a weekly review with the multidisciplinary foot team (MDFT) as and when required, until the ulcer is healed.

Supported self-care

Supported self-care with the patient should be an intended goal of the management strategy put in place by the MDFT. It is important that the patient's willingness and ability to engage in their own care is appropriately assessed. As stated in Munro et al (2021): "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.ahsnetwork.com/wp-content/uploads/2020/04/Shared-Care-for-Wounds-30.03.20.pdf>."

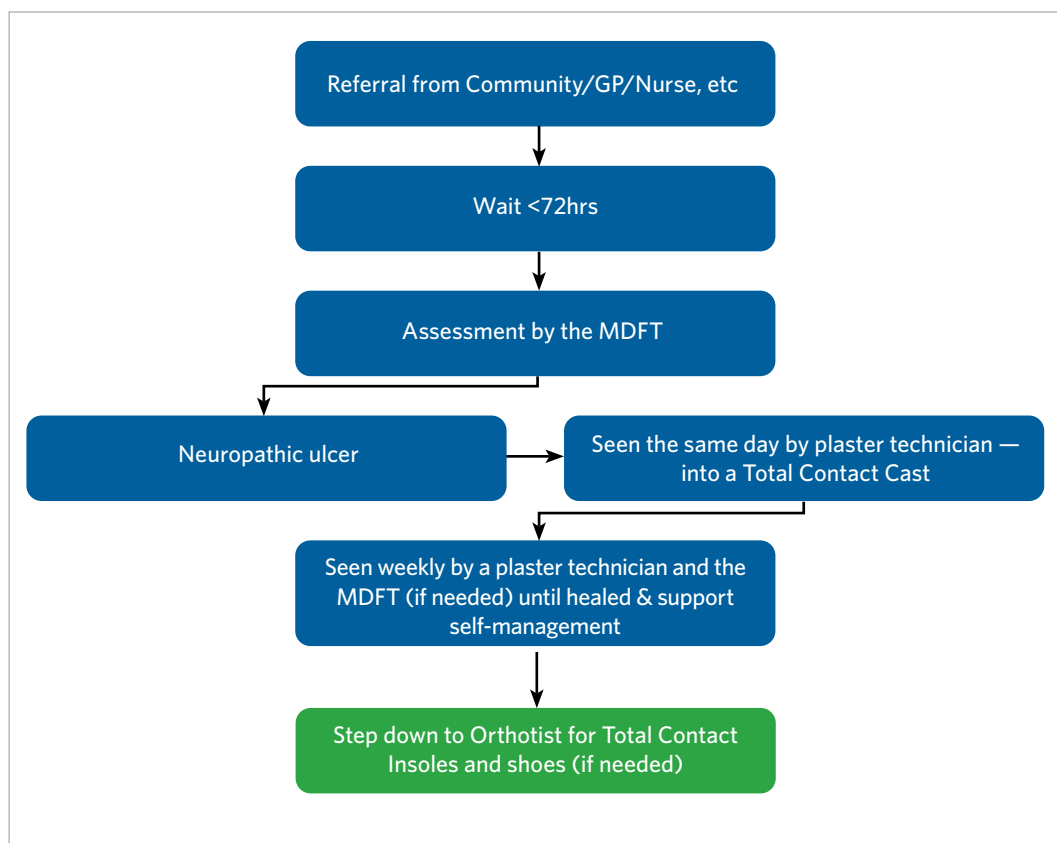


Figure 4. Clinical service pathway.

Summary and conclusions

Key points

- Bear in mind that it is reasonable to assume that even those individuals with full mental capacity may wish to remove the total contact cast for reasons that seem sensible to them at the time
- As TCC is the gold-standard treatment, it is vital that awareness and patient uptake is increased, to improve patient quality of life and outcomes.

“There is no such thing as the perfect offloading device for each and every individual” (Fife Health & Social Care Partnership, 2015). That said, TCC remains the gold standard and should be regarded as such when selecting the appropriate treatment for individuals with diabetes and a DFU. Patient preference should, therefore, be a central issue in selecting the most appropriate product. Clinicians should ensure that individuals with diabetes and an ulcer should be provided with all the facts, to enable them to understand and engage with their treatment, and make the correct informed choice.

An individual being treated with TCC should be informed that they should only return to the foot clinic for cast removal if there is a major problem (examples of which include swelling, excessive exudate occurrence and severe pain), while they should have access to a support number to allay any fears that may arise.

Every person is different, of course, but it would be reasonable to assume that even those individuals with full mental capacity may wish to remove the total contact cast for reasons that seem sensible to them at the time. Therefore, it is important for clinicians to communicate the consequences of taking off the total contact cast but, at the same time, also stressing where alternatives can be utilised, despite them not being as effective as TCC. It is vital to communicate that it is not safe for patients to remove the cast themselves and they must seek urgent assistance to do so, to prevent complications. People also need to have capacity to have the cast removed in the event of a suspected complication, e.g. a rise in blood glucose or experiencing pain.

Invariably, product suitability may alter as individual circumstances change and offloading devices must be utilised to reflect this. Where possible, future planning should be adopted to reduce costs and minimise misuse of products, while giving patients the best possible outcome in the shortest possible time. Offloading equipment must reflect the clinical needs of the patient and change in response to their level of risk and mobility.

As TCC is the gold-standard treatment, it is vital that awareness and patient uptake is increased, to improve patient quality of life and outcomes. The evidence base is clear and clinicians should embrace TCC and seek out the learning, confidence and competence to provide this essential service. These guidelines will offer some support and guidance in being confident in choosing suitable patients for TCC.

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