

 **National Plantar Ulceration Off Loading Pathway**

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 Plantar Ulceration

Initial Assessment:

**V**- What is the vascular state and is referral required to vascular team?

**I** – is the wound clinically infected requiring antibiotics?

**P**- if pressure was the cause has it been removed and treat as below to reduce pressure

Assess glycaemic control.

Consider surgical referral.

Neuropathic

Neuro/PAD

 **1st Line**

Forefoot Offloader

Soft Shell Immobilisation Boot

Non-pneumatic Immobilisation Boot

Dressing Shoe

TCC

or

Non-removable cast walker

 With suitable offloading insole

TCC or non –RCW

May be used with caution

(See guidelines)

 **If contra-indicated**

 **2nd Line**

Removable cast walker or Removable cast

 (With suitable offloading insole)

 **Temporary Measures/Exceptions 3rd Line**

 (NB clinical justification for use must be documented)

(3)

Foot Orthoses

(4)

Felt padding

(1)

Cast Shoe

(1)

Forefoot Offloading Shoe

 (2)

Temporary Footwear

 (3)

Softcast Devices

Introduction

The purpose of this document is to provide guidance to ensure the consistent and appropriate approach to offloading therapy for foot ulceration within NHS Wales. A large discrepancy exists between guidelines and clinical practice in off-loading diabetic foot ulcers. The morbidity and mortality associated with diabetic foot lesions remain extremely high (1), and ulcer free survival rates are poor. (2) Ulcer management needs to be optimized to ensure the best outcome.

 This document has been developed using the Consensus Guidelines by R J Snyder et al on The Management of Diabetic Foot Ulcers through Optimal Off-Loading (3), 2015 NICE Guidelines (4)and 2015 International Working Group on the Diabetic Foot (IGWDF) Guidance(5). These documents have undertaken systematic review and make recommendations based on the latest available evidence and the quality of that evidence. However they all recognise that the level of this evidence varies and further research is necessary. Unless otherwise referenced the recommendations in this document are taken from these three pieces of work.

Neuropathy, deformity and trauma are the most common causes of Diabetic Foot Ulceration (DFU). Evidence is clear that adequate off-loading increases the likelihood of DFU healing and that increased clinician use of effective off-loading is necessary. However recent United States and European surveys show a large discrepancy between guidelines and clinical practice in off-loading diabetic foot ulcers.

Once an ulcer has formed, unless the ulcerated area is off-loaded, healing may be chronically delayed, even in an adequately perfused limb. Clinicians must ensure adequate off-loading is maintained throughout the entire DFU treatment process. One–time prescription of off-loading is not a sufficient intervention. After an ulcer is healed, the risk of recurrence is high— 40% in a median 4 months in one recent study—showing the need for continuous off-loading in these patients.(6)

Whichever offloading modality is chosen, patient adherence to the treatment regime is crucial in preventing and healing foot ulcers. It is consistently reported that patients who do not adhere to an intervention present with poorer outcomes. It is incumbent upon the practitioner to educate the patient in the benefits and risks of effective offloading and the risks of non-compliance.

However, off-loading alone will fail to present optimal outcomes if vascular disease and/or infection are not managed appropriately. Many ulcers are indeed complicated by such factors as infection and vascular disease (6, 7) and the same expectations for time to heal cannot be applied to infected neuroischemic wounds. But off-loading is still important in such complex wounds—perhaps even more important—because of the enhanced risk of limb loss in these patients.

NICE Guidance recommends the use of the University of Texas ulcer classification system or SINBAD because they are simple and widely used in the UK.

This pathway is intended to give guidance to clinicians on the optimal use of off-loading for DFUs based on most current evidence and to ensure consistency of approach across Wales.

TOTAL CONTACT CASTING (TCC) and NON-REMOVABLE CAST WALKERS (Non-RCW)

Several RCTs have shown non-removable devices to be more effective than removable. The TCC has been regarded as the “gold standard” treatment option to effectively heal plantar forefoot DFUs. However, the prefabricated cast walker, fitted with an appropriate insole, has been shown to be as effective as the TCC when rendered irremovable. The non-removable cast walker (non-RCW) requires less technical skill and time to apply and plaster bandage or cable ties can be used to render it irremovable.

NICE guidelines state that for plantar neuropathic, non-ischaemic uninfected forefoot and mid-foot ulcers non-removable casting should be offered or an alternative offloading device until casting can be provided.

Total contact casts (TCCs) and non- removable walkers have been shown to be extremely effective in off-loading the diabetic foot. TCC and RCWs immobilize the ankle reducing forefoot propulsion pressure from the propulsion phase of gait. They redistribute load to the device itself. They also reduce the stride length, which decelerates the foot and reduces the force applied to the foot. The walls of the TCC have been shown to bear approximately 30% of the load. The foot is suspended by the load bearing capacity of the TCC walls and this contributes to the pressure reduction and redistribution properties of the TCC. (8)

TCC and non-RCWs can be used to offload the heel but are generally more effective at offloading the forefoot.

Suitability

TCC or non-RCW are the preferred method for offloading neuropathic plantar forefoot/midfoot DFUs without ischaemia or uncontrolled infection because they have most consistently demonstrated the best healing outcomes and are a cost-effective treatment.

Non-RCWs may be considered in patients with mild infection or mild PAD i.e. present to a level that there is potential for wound healing. Do not use when both mild infection and mild PAD are present. It is less suitable for heavily exuding ulcers or active infections not under control requiring frequent local care or inspection.

A cast walker may not accommodate a wide or deformed foot shape.

TCCs can be supplied with an overshoe which can be removed before going to bed. This is not the case for a cast walker which could create cleanliness issues for patients.

The choice of off-loading modality should be determined by the patient’s physical characteristics and ability to comply with treatment as well as by the location and severity of the ulcer.

Patient adherence is the key to ensuring effective adequate off-loading. Non-removable devices are most effective regarding patient adherence. Careful patient counselling is needed by the practitioner with possible adverse effects of any interventions being considered and discussed with the patient.

If use of TCC or non-RCW is contraindicated the reason must be documented in the patient records. Patient refusal to comply with treatment, their reason for refusing and the potential consequences of refusing treatment must be documented in patient records.

Adverse Effects

Possible adverse effects of non-removable knee high devices include ankle joint immobilisation, reduced activity level, potential risks of falls, and knee or hip complaints from unequal limb length and pressure ulcers due to poor casting or fitting. All practitioners applying a cast must be competent to ensure complications that can be associated with a cast are minimised. All injuries must be recorded on Datix.

Weekly changes of TCC are recommended to counter any oedematous changes in the affected limb. Cast Walkers, whether removable or rendered non-removable, may not be wide & deep enough to accommodate a deformed and/or swollen foot.

Ensure protection of the contra-lateral limb which may be vulnerable to excessive forces leading to ulceration. Consider appropriate footwear for the contra-lateral limb and the use of an offloading insole if appropriate. Walking aids may help to offload extra pressure on the contra-lateral limb.

Walking aids may be used to address stability issues, allowing these patients to be casted. Consider the use of temporary shoe raise devices to overcome limb length problems.

Patients should be issued with an appropriate advice sheet with out of hours emergency procedures. They should be advised not to drive because their insurance will be invalidated.

REMOVABLE CAST WALKERS (RCW)

Effective healing with removable devices is totally dependant on a high level of patient compliance. The possibility of non adherence should always be considered when providing removable devices. One study found that patients used their prescribed removable device for an average of only 29% of their total daily number of steps. (9) If a device is not worn it cannot be effective.

 It must also be taken into account that RCW may not be wide & deep enough to accommodate a deformed and/or swollen foot. Patients may not be consistent in achieving the correct level of inflation with pneumatic linings.

RCW should only be considered after TCC/Non RCW have been considered and excluded as contra-indicated. RCW should also be fitted with an appropriate insole.

Suitability

The use of non-removable devices is contra-indicated with untreated infection or osteomyelitis and in patients with severe peripheral arterial disease. In these circumstances the RCW and an appropriate insole can be used to offload the affected area. However, when the infection is controlled or with patients with mild PAD but the potential for healing, non-removable offloading is more appropriate.

Heavily exudating plantar ulceration requiring frequent local care or inspection may also be better suited to the use of removable devices until the exudate is under control.

Patients may prefer the use of a removable device because it is more practical for daily activities and practitioners because of the ease of application. However patient compliance must always be considered.

EXCEPTIONS/ TEMPORARY MEASURES

The interventions identified in this section should only be selected in cases where the use of TCC & Non-RCW have been considered and excluded as contraindicated or until they can be implemented. These should be the exception and not the rule, as it is well documented that the non removable modalities are the most successful in healing ulcerations and that the average cost of treatment of ulcer patients can be halved when used, compared with those not treated with a non removable modality.

Where exceptions/temporary measures are implemented, justification for not using the high level evidenced treatments should be clearly documented in the patient’s records.

Treatment options need to be discussed with the patient and the reason for the chosen treatment modality must be explained to the patient clearly and documented in the notes.

It is important to recognise that the longer healing times associated with these modalities poses a higher risk of infection and hospitalisation and this must be explained to the patient and documented in the notes.

Whichever treatment modality is selected it is vital to ensure protection of the contra-lateral limb which may be vulnerable to excessive forces leading to ulceration. Consider appropriate footwear for the contra-lateral limb and the use of an offloading insole if appropriate. Walking aids may help to offload extra pressure on the contra-lateral limb.

Cast Shoe

A cast shoe is a removable plaster or fibreglass cast. Examples are Scotch cast boot, Ransart boot and MABAL cast shoe.

The Scotch-cast boot is a removable well-padded cast cut away at the ankle, leaving the ankle mobile. Windows are cut over the ulcers if needed. For large heel ulcers, a removable heel cup of fibreglass is added. The boot is worn with a cast sandal/walker boot.

A Ransart boot is a removable fibreglass combi-cast shoe extending to just below the ankle, existing of minimal padding and moulded to the shape of the foot with total contact to the entire plantar surface. A window is cut over the ulcer site.

A MABAL cast shoe is a removable fibreglass combi-cast shoe consisting of minimal padding, a rigid sole with total contact of the entire plantar surface and a soft cast upper part extending to just below the ankle leaving the ankle mobile. A plastic roller sandal is worn underneath the shoe to facilitate walking.

While there is anecdotal evidence of their effectiveness, we have been unable to identify any published research investigating the effectiveness of cast shoes. There is, therefore, insufficient evidence to recommend for, or against their use.

As a removable device, the cast shoe is likely to suffer from poor patient adherence and, as there is no opportunity for load to be borne by the side walls of the cast, pressure can only be redistributed across the plantar surface. The cast shoe is expected, therefore, to be less effective than TCC, Non-RCW and RCWs. Further research in this area is required.

Forefoot Offloading Shoe

The forefoot offloading shoe can only offload the plantar forefoot and therefore should not be considered for ulcerations elsewhere.

A cushioning liner should be inserted where possible, to further aid offloading.

Caution is required when considering its use due to the negative rocker as this can cause instability. It is contra-indicated in equinus, and for patients with shuffling gait. A temporary shoe raise device should be used for the contra-lateral limb to reduce this effect but patients’ stability needs to be carefully considered prior to its issue.

Patients should be advised on how to walk in the shoe, as they must walk on the heel and midfoot only, for the shoe to have any offloading effect.

Temporary Footwear

Temporary footwear is a shoe that is pre-fabricated and used temporarily to accommodate bulky dressings or insoles applied to manage ulceration.

The systematic reviews were unable to identify any evidence to support the use of temporary footwear as an off-loading modality. Again there is anecdotal evidence only and as such, should only be used in exceptional circumstances with justification for their use in the treatment of plantar ulcerations.

The footwear should always have an offloading orthotic/insole to further reduce plantar pressures.

Temporary footwear may be helpful in the management of dorsal, medial or lateral foot ulceration, to reduce pressure from footwear.

 Foot Orthoses

There is a distinct lack of evidence for their use alone in this area.

There is only anecdotal evidence to suggest that orthoses may be helpful in healing superficial plantar neuropathic ulcerations.

Orthoses alone should therefore be a temporary measure or used **ONLY** in exceptional circumstances with justification for their use in the treatment of plantar ulcerations.

Orthotic intervention does however have strong evidence to support their use in preventing ulceration and post healing for reducing recurrence, particularly when used with custom footwear.

Shoe modifications, temporary footwear, toe spacers or orthoses could be considered to offload non plantar ulcerations without ischaemia or uncontrolled infection but there is only weak evidence to support this.

Softcast Devices

None of the above documents recommend the use of soft cast devices i.e. the slipper cast also known as focused rigidity casting.

However there is some anecdotal evidence to support use of the heel cast in managing heel ulceration. (10) The device is designed to remove point pressure, which can be a cause of delayed ulcer healing, by offloading the heel ulcer, and be removable to facilitate redressing of the ulcer. All practitioners applying a cast must be competent to ensure complications that can be associated with a cast are minimised.

Contraindications may include:-

* Critical lower limb ischemia
* Non-compliant patients
* Patients with conditions that may affect their stability in the device

It is important when using soft cast devices that the patient, carer or guardian is able to take the device on and off as required or that arrangements have been made with district or practise nurses to provide redressing. Verbal and written advice must be given to the patient/carer with emergency contact details.

Felt Dressings

Despite a lack of well-designed controlled studies, there is anecdotal evidence to support the use of felt and foam dressings. Any benefit will likely outweigh the harm, since studies have reported no complications.

The costs are relatively low but it does require frequent replacement. It should only be used in addition to appropriate footwear, walkers or cast and not as a single treatment modality unless other forms of offloading are not available.

Therapeutic footwear

There are no studies that show the efficacy of conventional or therapeutic footwear to heal neuropathic plantar foot ulcers.

However there are studies to support the use of therapeutic footwear in extending the period between episodes of ulceration if the shoes are worn daily both at home and outside. The incidence of re-ulceration has been shown to be halved in patients wearing prescription footwear for more than 9.6 hours per day, while patients not reaching this threshold derive little or no benefit from its provision (11).

At risk patients must always be advised to wear properly fitting footwear and not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside.

Heel Offloading Shoe

There appears to be no evidence available for the effectiveness of the Heel Offloading shoe.

Surgical Offloading Interventions

There is some evidence that when conservative treatment fails surgical intervention can be effective. Surgical offloading techniques that could be considered include TA lengthening, joint arthroplasty, metatarsal head resection or osteotomy and digital flexor tenotomy. However, when compared to conservative treatment, surgical offloading has been shown to be more effective in delaying recurrence than in healing foot ulcers.

Pathway guidelines for the ischaemic or neuro-ischaemic diabetic foot

Offloading studies have mainly focused on non-complicated neuropathic plantar ulceration. There is a shortage of high quality studies on offloading the ischaemic foot. The Consensus Guidelines, IWGDF and NICE guidelines all recommend TCC and non-RCW for the treatment of non-infected, non-ischaemic plantar ulcers. However, even though biomechanically, offloading is indicated for the majority of ulcers, in practice not all patients fit these criteria. Peripheral Arterial Disease (PAD) and/or infection will be seen in many patients and is thought of as a contradiction to casting.

A foot is considered to be ischaemic when the ankle pressure is <80mmhg or toe pressure <45mmhg. (12, 13) Applying a TCC to an ischaemic/neuroischaemic ulcerated diabetic foot should be used with caution and be applied and closely monitored by a skilled and competent practitioner. (14)

TCCs should not be used on such patients who also present with infection/sepsis within the wounds. This should be treated appropriately prior to considering applying a TCC.

The IWGDF recommend using the PEDIS or the ISDA grading for infection as it is universal. Clinicians should select and routinely use the validated classification system, to classify infections and to help define the mix of types and severity of their cases (see below).

Evidence of infection is defined by the presence of at least 2 of the following signs:

* Local swelling or induration
* Erythema
* Local tenderness or pain
* Local warmth
* Purulent discharge (thick, opaque to white or sanguineous secretion)

Mild infection is defined as local swelling, erythema >0.5cms to ≤2cm, local pain tenderness. Severe infection is defined as local tenderness or pain, purulent discharge. (14)

The practitioner should take into account the wound type, site, patient preference/suitability and use the offloading technique that has the lowest acquisition costs appropriate to the clinical circumstances.

The patient should also be issued with verbal and written information on emergency procedures with contact names and numbers if any adverse effects should occur whilst wearing a TCC.

All TCCs should be removed and renewed at least once a week by an appropriately skilled health professional to review wounds and redress.

SUMMARY

1. The evidence is clear that offloading increases the likelihood of ulceration healing.
2. The discrepancy between evidence and practice needs addressing.
3. Non-removable devices should always be the first consideration.
4. The appropriate form of offloading must be continued **throughout** the healing process.
5. Removable devices are **only** to beused when TCC & Non-RCW have been considered and excluded as contraindicated.
6. The reasons for the choice of offloading device must always be clearly documented in the patient’s notes.
7. The advantages/disadvantages and possible complications of each offloading therapy must be explained to the patient and documented in the notes.
8. The advantages/disadvantages and possible complications of refusing offloading therapy must be explained to the patient and documented in the notes.
9. Patient compliance/adherence or lack of must always be clearly documented in the notes.
10. Poor adherence, by patient or practitioner, to an offloading intervention is associated with longer healing times, increased risk of infection and poorer outcomes.
11. Infection and /or vascular disease must be managed.
12. Protect the contra-lateral limb with appropriate footwear and offloading.
13. Therapeutic Footwear/insoles may reduce the ulcer recurrence rates when the ulceration is healed but should not be a first line treatment for healing ulceration.
14. Provide stability devices if necessary.

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|  | Method | Forefoot | Midfoot | Heel | Intervention | Comments |
|  | TCC |  |  |  | 1st line | Strong evidence that TCCs heal neuropathic ulcers faster than other offloading modalities |
|  | Non-RCW |  |  |  | 1st line | Removable cast walker fitted with an appropriate insole has been found to be as effective as the TCC when rendered irremovable. Can be used with mild infection or mild PAD but not both. |
|  | RCW with insole |  |  |  | 2nd Line | Effectiveness dependent on patient compliance but associated with lower healing rates than non-RCWCan be used on infected and ischaemic wounds |
|  | Removable TCC |  |  |  | 2nd Line | As above |
|  | Scotch Cast |  |  |  | 3rd line or temporary | Lighter and stronger than plaster of paris casts, padded cast covering foot and ankle, can be made non-removable.Evidence limited |
|  | Forefoot offloading Shoe |  |  |  | 3rd line or temporary | Caution needed because negative rocker can cause instability  |
|  | Heel offloading shoe |  |  |  | 3rd line or temporary | No evidence |
|  | Temporary DB shoe with insole |  |  |  | 3rd line or temporary | Evidence mainly anecdotal |
|  | FootOrthoses |  |  |  | 3rd line or temporary | Generally used in conjunction with other offloading methods |
|  | Felt padding |  |  |  | 3rd line or temporary | Mainly a temporary measure or used with other offloading methods. Quality of evidence is low and studies limited. |
|  | Softcast |  |  |  | 3rd line or temporary | Evidence mainly anecdotal |

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