Practical considerations for implementing the new IWGDF guidelines for offloading diabetic foot ulcers

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Evidence-based guidelines, such as those provided by the International Working Group on the Diabetic Foot (IWGDF), are essential to support high-quality clinical management and outcomes of diabetic foot ulceration. However, variations in clinical outcomes across the UK and the world indicate that guidelines may not be fully implemented in clinical practice. This paper discusses practical considerations when applying the new IWGDF guidelines on offloading foot ulcers. The authors anticipate that this paper will support clinicians, managers and policymakers to benchmark their current approach to offloading treatments against these new recommendations. Implementing these recommendations into clinical practice, using the flow chart provided to guide every patient assessment, should help ensure that every patient is offered the most effective evidence-based offloading treatment. This, in turn, should help reduce variations in diabetic foot ulcer management and outcomes.

Evidence-based guidelines are essential to support high-quality clinical management and outcomes for people with diabetic foot ulceration (DFU). However, large variability in DFU and amputation outcomes remains in the UK and across the world (Health and Social Care Information Centre, 2019; Zhang et al, 2020). This may in part be explained by the fact that existing guidelines, including those on offloading, are not fully implemented in practice (Prompers et al, 2008; Wu et al, 2008; Paisey et al, 2018). Thus, there seems to be a need for more practical advice for clinicians on how to implement current offloading guidelines. This paper describes the new International Working Group on the Diabetic Foot (IWGDF) guideline on offloading DFU and discusses practical considerations for implementation.

IWGDF recommendations on offloading DFUs

Clinical management of DFUs typically includes a multidisciplinary approach addressing ischemia, infection, metabolic control, debridement and wound care. In addition to this, offloading, that is, "the relief of mechanical stress (pressure) from a specific region of the foot" (Bus et al, 2020a), is a cornerstone of DFU management and can be achieved with a number of different non-surgical and surgical interventions (*Table 1*).

In *Table 2*, the authors have reproduced each IWGDF offloading recommendation with the GRADE strength of recommendation and quality of evidence grades (Bus et al, 2020b). For each recommendation we have outlined several practical considerations to facilitate their implementation. To provide an easy overview and help busy clinicians quickly interpret the recommendations, we have also reproduced the flow diagram from the original guideline (Bus et al, 2020a) (*Figure 1*).

Practical considerations for implementing recommendations

Table 1. Categorisation of offloading interventions according to the International Working Group of the Diabetic Foot.

Non-surgical offloading intervention			Surgical offloading techniques
Offloading devices (ankle- and knee-high, removable and non-removable)	**Footwear (shoe-gear including insoles)**	**Other offloading techniques**	E.g., Achilles tendon lengthening, metatarsal head resection, osteotomy, arthroplasty, ostectomy, exostectomy, external fixation, flexor tendon transfer or tenotomy, silicone injections, and tissue augmentation.
E.g., total contact cast, (non-) removable knee-high walker, removable ankle-high walker, forefoot offloading shoe, cast shoe*, healing sandal, postoperative healing shoe, and custom-made temporary shoe.	E.g., conventional footwear, and standard (off-the-shelf) or custom-made therapeutic footwear.	E.g., bed rest, crutches, wheelchairs, offloading dressings, felted foam/padding, callus debridement, gait retraining, foot-related exercises, and patient education.	

**Removable plaster or fibreglass cast that extends to just below or at the ankle joint.*

Table 2. International Working Group on the Diabetic Foot (IWGDF) recommendations on offloading diabetic foot ulcers (Bus et al, 2020a).

Recommendations	GRADE strength of recommendation	Quality of evidence
1A. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, use a nonremovable knee-high offloading device with an appropriate foot-device interface as the first choice of offloading treatment to promote healing of the ulcer.	Strong	High
1B. When using a nonremovable knee-high offloading device to heal a neuropathic plantar forefoot or midfoot ulcer in a person with diabetes, use either a total contact cast (TCC) or nonremovable knee-high walker, with the choice dependent on the resources available, technician skills, patient preferences, and extent of foot deformity present.	Strong	Moderate
2. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for whom a non-removable knee-high offloading device is contraindicated or not tolerated, consider using a removable knee-high offloading device with an appropriate foot-device interface as the second choice of offloading treatment to promote healing of the ulcer. Additionally, encourage the patient to wear the device at all times.	Weak	Low
3. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for whom a knee-high offloading device is contraindicated or not tolerated, use a removable ankle-high offloading device as the third choice of offloading treatment to promote healing of the ulcer. Additionally, encourage the patient to wear the device at all times.	Strong	Low
4A. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, do not use, and instruct the patient not to use, conventional or standard therapeutic footwear as offloading treatment to promote healing of the ulcer, unless none of the above mentioned offloading devices is available.	Strong	Moderate
4B. In that case, consider using felted foam in combination with appropriately fitting conventional or standard therapeutic footwear as the fourth choice of offloading treatment to promote healing of the ulcer.	Weak	Low
5. In a person with diabetes and a neuropathic plantar metatarsal head ulcer, consider using Achilles tendon lengthening, metatarsal head resection(s), or joint arthroplasty to promote healing of the ulcer, if non-surgical offloading treatment fails.	Weak	Low
6. In a person with diabetes and a neuropathic plantar or apex digital ulcer, consider using digital flexor tenotomy to promote healing of the ulcer, if non-surgical offloading treatment fails.	Weak	Low
7A. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischaemia, consider using a nonremovable knee-high offloading device to promote healing of the ulcer.	Weak	Low
7B. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both mild infection and mild ischaemia or with either moderate infection or moderate ischaemia, consider using a removable knee-high offloading device to promote healing of the ulcer.	Weak	Low
7C. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both moderate infection and moderate ischaemia or with either severe infection or severe ischaemia, primarily address the infection and/or ischaemia, and consider using a removable offloading intervention based on the patient's functioning, ambulatory status, and activity level, to promote healing of the ulcer.	Weak	Low
8. In a person with diabetes and a neuropathic plantar heel ulcer, consider using a knee-high offloading device or other offloading intervention that effectively reduces plantar pressure on the heel and is tolerated by the patient, to promote healing of the ulcer.	Weak	Low
9. In a person with diabetes and a nonplantar foot ulcer, use a removable ankle-high offloading device, footwear modifications, toe spacers, or orthoses, depending on the type and location of the foot ulcer, to promote healing of the ulcer.	Strong	Low

Figure 1. Flow diagram on the recommended offloading treatment for a person with diabetes and a foot ulcer. Reproduced from (Bus et al, 2020a) with permission.

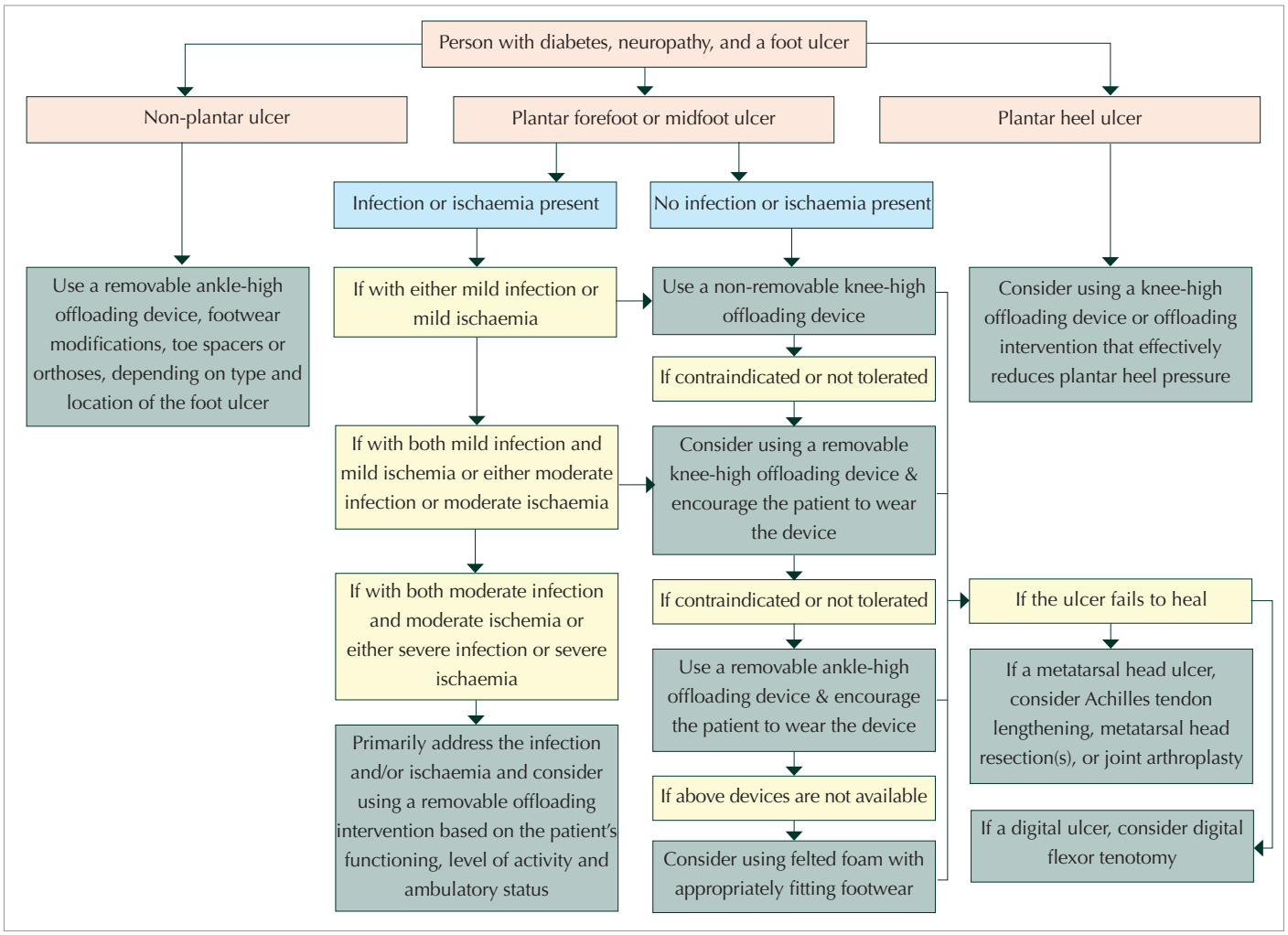
Recommendations 1A and 1B

Based on the best available evidence the IWGDF guideline strongly recommends the use of either a total contact cast (TCC) or non-removable knee-high walker as the first choice of offloading intervention for plantar neuropathic DFU. Yet TCCs are typically not widely used in practice (Prompers et al, 2008; Wu et al, 2008) and the reasons for this include a lack of access to training, time, resources and healthcare reimbursement systems, plus concerns over iatrogenic lesions. Hence, confirmation that non-removable knee-high walkers (prefabricated walkers rendered irremovable) are as effective as a TCC to heal DFU should provide clinicians with a more practical alternative to ensure optimal offloading.

To render knee-high walkers non-removable is a relatively simple process and clinicians have adopted a range of solutions, such as a layer of casting material over the boot (Armstrong et al, 2002) or fastening with a cable tie or plastic band (Piaggesi et al, 2016). The advantages of non-removable walkers are that they require minimal training to apply and do not require any specialist equipment to remove. Also, the total treatment cost is lower with knee-high walker as they do not need replacing every time, and appointment times can be shorter than when applying a TCC (Lazzarini et al, 2020).

However, in the presence of significant deformity, prefabricated walkers may not be suitable and may increase the risk of iatrogenic lesion; a custom-made device, such as a TCC, is then indicated. Additionally, heavily exudating DFUs may need initial treatment with a removable device to allow for more regular dressing changes, with patients transferred into a non-removable device as exudate levels become more manageable.

The use of any type of non-removable device requires thorough patient education on the



potential benefits and risks. Patients need to be advised to monitor the device and the limb, and be provided with information on what to do in the event of a problem, including 24-hour contact for patients fitted with a TCC. Consideration should also be given to the contralateral foot and any limb-length discrepancies managed with either a shoe raise or simple prefabricated shoe-lift device that can be attached to the bottom of the shoe. Patients may need additional walking supports, such as crutches or sticks, to reduce instability and the risk of falls. It is also useful to recommend that the patient wear a sock on the contralateral foot when sleeping to protect it from rubbing on the device.

Recommendation 2

When non-removable knee-high devices are contraindicated, for example, by moderate-to-severe infection and/or ischaemia (see recommendations 7A, 7B and 7C), or the DFU requires more frequent inspection a removable knee-high device should be recommended. Sometimes patients may also decline a non-removable device if they need to drive using the foot with the device, or need to be away from the clinic for prolonged periods meaning they are unable to attend regular clinical appointments to have their non-removable device and DFU checked, such as on holidays or during pandemics. Symptoms of painful peripheral neuropathy may also be exacerbated by knee-high devices and patients may prefer removable devices.

Removable knee-high devices come in a variety of forms. A bivalved TCC is a TCC that is cut open to produce a two-part TCC secured with Velcro straps. A Charcot restraint orthotic walker (CROW) is similar in design to a bivalved TCC, being custom-made with two parts secured with Velcros. There are also a number of different prefabricated walkers available which are typically used more in clinical practice than bivalved TCC or CROWs. There is currently no evidence for choosing one removable knee-high device over another and each device has different advantages and disadvantages. An advantage of custom-made devices (bivalved TCC and CROW) is that they can accommodate significant deformity or oedema. Their disadvantages are the time and expertise needed to produce them. An advantage of bivalved TCC is that it has a lower weight than a CROW. However, (custom and prefabricated) removable knee-high devices have shown inferior efficacy to heal ulcers compared with equivalent non-removable devices (Lazzarini et al, 2020), presumably because adherence to using the devices is lower (Armstrong et al, 2003). Thus, it is essential to discuss the importance of adherence with patients when prescribing removable devices, and be upfront with the challenges to adherence that may come in everyday life, such as, putting on the device in the middle of the night when visiting the bathroom. Patients also need to be advised that choosing a removable device is likely to extend treatment times and, thus, increase the risk of wound complications.

Recommendation 3

Removable ankle-high offloading devices should only be considered when there is a contraindication or the patient is unwilling to use a knee-high device. Contraindications to using a knee-high device can include other ulcers or sensitive skin on the lower leg, or severe infection or ischaemia (see recommendations 7A, 7B, and 7C). Balance issues are also common in people with severe peripheral neuropathy and prescribing a device that may make these problems worse by immobilising the ankle joint may result in low adherence (Crews et al, 2016) or falls. Thus, it is suggested that the patients are screened for falls risk and that appropriate assistive devices, i.e. crutches, walking sticks, or walking frames are provided if needed.

There are a variety of ankle-high devices available (ankle-high walker, forefoot offloading shoe, cast shoe, healing sandal, postoperative healing shoe, and custom-made temporary shoe) and the choice of device should be based on individual patient assessment and availability. Ankle-high devices generally reduce plantar forefoot pressures less than knee-high devices, and some ankle-high devices can be challenging to walk in and result in lower adherence and increased risk of falls. An above the ankle-high device, such as a low-cut walker, is typically more effective at reducing plantar pressure than a below ankle-high device (Crews et al, 2012). As with any removable device, it is important to discuss the importance of adherence with patients.

Article points

1. The first choice for offloading a neuropathic non-ischaemic non-infected plantar foot ulcer is a non-removable knee-high offloading device.
2. The second- and third choices are a removable knee-high offloading device and removable ankle-high offloading device, respectively.
3. The fourth choice is therapeutic footwear in combination with felted foam, but only when no other offloading device is available.
4. If non-surgical offloading fails to heal ulcers consider using a surgical offloading procedure, such as a tenotomy or metatarsal head resection.
5. For treating a non-plantar foot ulcer, consider using either a removable ankle-high offloading device, footwear modification, toe spacer, or other orthosis.

Recommendations 4A and 4B

As highlighted in the flow diagram (*Figure 1*), felted foam in combination with conventional or standard therapeutic footwear is the least effective offloading device. It should not be used unless all other options are either not available or have been exhausted. Patients should be informed that its use is likely to result in prolonged healing times compared to other offloading devices. Importantly, felted foam compresses over a relatively short period of time and, thus, the offloading effect diminishes within days and this is why it needs to be replaced approximately every third day (Zimny et al, 2001). Multiple trials have also consistently shown that therapeutic footwear alone as an offloading intervention is less effective than offloading devices to heal DFUs (Health Quality Ontario, 2017; Morona et al, 2013), and thus it is not recommended.

Recommendation 5

In some cases, non-surgical offloading is not sufficient to heal a neuropathic plantar metatarsal head ulcer. This may be because the device is not appropriately offloading the ulcer, adherence is low, or a combination of both. In these cases, surgical offloading using Achilles tendon lengthening, metatarsal head resection(s), or joint arthroplasty should be considered. However, surgical offloading is contraindicated when severe ischaemia is present and any severe ischaemia should be primarily addressed before any surgical offloading procedures are considered.

The advantage of surgical compared to non-surgical offloading, is that it is permanent. Still, success of any surgical procedure will likely be dependent on the patient following the advice immediately post operatively and in the long-term following advice on footwear and podiatry to prevent re-occurrence. The disadvantage is the inherent risks of surgery; non-surgical offloading should be the first selected offloading option. Evidence demonstrates that knee-high offloading devices are still more effective than surgical offloading procedures in the first instance. Before proceeding to surgery, it is important to ensure a thorough assessment of the patient's suitability and fitness is carried out and that the patient understands the potential risks of surgery (postoperative complications, infection, gait problems, acute Charcot foot, ruptured Achilles tendons, and transfer ulcers; Wieman et al, 1998; Holstein et al, 2004; Molines-Barroso et al, 2013)

Recommendation 6

As with plantar metatarsal head ulcers (Recommendation 5), some plantar or apex digital ulcers do not heal with non-surgical offloading and surgery should be considered. These ulcers are typically associated with hammer toe deformity which result in high pressure on the apex of the toe. These deformities can be corrected with percutaneous digital flexor tenotomy, which is a minimally invasive procedure that can be performed in an outpatient setting without need for subsequent immobilisation. A systematic review reported on overall healing rate of 97% following this procedure (Bonanno and Gillies, 2017), but patients should also be informed on the risks for infection and transfer lesions.

Recommendations 7A, 7B and 7C

Few DFUs are purely neuropathic, and the status of a DFU can change and therefore it is important to regularly review and adapt the approach to off-loading. Both moderate-to-severe infection and/or ischaemia increase the risk of rapid deterioration of the foot and ulcer and, thus, removable devices may be preferable to allow frequent inspection of the foot and ulcer. However, in cases of mild infection or ischaemia, non-removable devices can still be used. Regardless, all these plantar DFUs need optimal offloading to heal. Once the underlying infection or ischaemia has been successfully resolved then the approach to offloading can be re-evaluated and where it is appropriate, non-removable devices should be considered as the first choice for offloading.

Recommendation 8

Plantar heel ulcers are considered more difficult to offload and heal than plantar forefoot ulcers (Bus et al, 2008). One study found shorter time-to-healing with TCC than therapeutic footwear for plantar heel ulcers (Ganguly et al, 2008) and there is some evidence that knee-high devices reduce plantar heel pressures more than other offloading interventions (Lazzarini et al, 2020). Given this scarcity of evidence, the guideline recommends

knee-high offloading devices or other offloading interventions that have demonstrated reduction of heel pressure and are tolerated by the patient (Bus et al, 2020a).

Recommendation 9

Non-plantar ulcers are not exposed to stress directly from the ground but may be exposed to stress from the footwear or — in the case of interdigital ulcers — from adjacent toes. For example, a tight shoe box may cause pressure on the foot margin and interdigital ulcers, ill-fitting footwear may cause shear on the posterior heel, and a hallux valgus deformity causes pressure between the first and second toe. Different devices can be used to reduce the mechanical loading on non-plantar ulcers and the choice will often depend on the location of the ulcer. Sandals or shoes with a wide toe-box and toe-spacers can be used to offload interdigital ulcers. The shoe's upper can be stretched or holes can be cut in it to offload ulcers located on the medial, lateral, or dorsal aspects of the foot, or if adaptions to the shoe are not possible then a sandal will alleviate pressure from the toes.

Non-plantar heel ulceration presents a considerable challenge to clinicians and are associated with long time to healing (Jeffcoate et al, 2017). This is due both to the location of the ulcer and the characteristics of people who present with heel ulceration: older with extensive comorbidity (Örneholm et al, 2017). In case of an ulcer at the posterior heel, it may be necessary to stretch the material or cut a hole in the heel counter to relieve pressure on the ulcer and to implement heel offloading devices for when the patient is lying in bed as well, such as heel wedges (McGinnis and Stubbs, 2014). Custom-made, fibreglass heel casts are widely used in the UK and elsewhere, but a high-quality trial found they were not associated with improved healing (Jeffcoate et al, 2017).

Discussion

This article has provided some practical strategies for clinicians to consider when implementing the recommendations from the new IWGDF guideline on offloading treatment. The authors hope this will improve the utilisation of evidence-based offloading interventions and in turn significantly improve healing outcomes for patients. As a starting point, every patient attending with a DFU should be assessed for and if suitable offered a non-removable offloading device as the first-choice treatment for a plantar neuropathic ulceration. The authors highlight that this recommendation does not only include using TCCs as historically recommended, but also non-removable knee-high walkers, which are as effective for healing as TCCs, but easier to apply and more cost-effective. These new IWGDF guidelines are the first to provide specific recommendations to clinicians on how to offload infected and ischaemic ulcers.

There needs to be a concerted effort to work towards developing resources for clinicians and patients to support and inform decisions on offloading, such as the flow diagram in *Figure 1*. Using such a standardised and evidence-based approach to choosing offloading is one factor that could help address the variation in ulcer healing and amputation rates that has consistently been seen across the UK and the world.

Readers are referred to the IWGDF website, *https://iwgdfguidelines.org*, for the full offloading guideline and the other six guideline documents (Practical guidelines, Prevention, Peripheral artery disease, Infection, Wound healing interventions, and Classification).

Conclusion

The new IWGDF offloading guideline is a valuable resource for clinicians working with DFU. The authors hope that the current paper can support the clinical implementation of the guideline and, thereby, contribute to reduced variations in management and improved clinical outcomes. ■

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