IWGDF Guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes

Prepared by the IWGDF Working Group on Footwear and Offloading

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Recommendations

Casting and prefabricated healing devices

1. To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot-device interface. (GRADE recommendation: strong, Quality of evidence: high)

2. When a non-removable knee-high device is contraindicated or not tolerated by the patient, consider offloading with a removable knee-high walker with an appropriate foot-device interface to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only when the patient can be expected to be adherent to wearing the device. (Weak; Moderate)

3. When a knee-high device is contraindicated or cannot be tolerated by the patient, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only and when the patient can be expected to be adherent to wearing the shoes. (Weak; Low)

Therapeutic footwear

4. To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside (Strong; Low).

5. Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis. (Strong; Low)

6. To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking (i.e. 30% relief compared to plantar pressure in standard of care therapeutic footwear), and encourage the patient to wear this footwear. (Strong; Moderate)

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7. Do not prescribe, and instruct a patient with diabetes not to use, conventional or standard therapeutic shoes to heal a plantar foot ulcer. (Strong; Low)

8. Consider using shoe modifications, temporary footwear, toe spacers or orthoses to offload and heal a non-plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. The specific modality will depend on the type and location of the foot ulcer. (Weak; Low)

Surgical offloading interventions

9. Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection, or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar foot ulcer. (Weak; Low)

10. Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the toe. (Weak; Low)

11. To heal a neuropathic plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes, consider Achilles tendon lengthening, single or pan metatarsal head resection, or joint arthroplasty when conservative treatment fails. (Weak; Low)

12. To heal a toe ulcer without ischemia or uncontrolled infection in a patient with diabetes and hammertoes, consider digital flexor tenotomy when conservative treatment fails. (Weak; Low)

Other offloading interventions

13. If other forms of biomechanical relief are not available, consider using felted foam in combination with appropriate footwear to offload and heal a neuropathic foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. (Weak; Low)

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Consideration about side effects / complications

It is important that consideration is given to possible adverse effects of some of the above-mentioned interventions, which include the use of non-removable and removable knee-high offloading devices, and all surgical offloading procedures. These possible adverse effects, discussed below, should be discussed with the patient for informed shared-decision making.

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Introduction

Foot ulcers are a major complication of diabetes mellitus and are associated with high morbidity, mortality, and costs.[1-3] Yearly incidence is estimated to be around 2% in patients with diabetes,[4] but this increases substantially when patients successfully heal from a foot ulcer, with reported recurrence rates between 30% and 40% in the first year.[5,6] Prevention and adequate treatment of these ulcers is therefore of paramount importance.

Risk factors

Peripheral neuroqpathy affects approximately half of people with diabetes mellitus and leads to loss of protective sensation in the feet, which is one of the most important risk factors for ulceration.[3,7] In the presence of loss of protective sensation, elevated levels of mechanical pressure can contribute to the development of foot ulcers in diabetic patients.[7-9] High foot pressure is itself significantly associated with foot deformity and structural changes in soft tissue.[10] From this, it can be inferred that the combination of foot deformity, loss of protective sensation, inadequate off-loading, and a minor trauma leads to tissue damage and ulceration. And once an ulcer has formed, healing may be chronically delayed, if the area it not effectively offloaded.

Interventions

There is a long clinical tradition in the use of casting, footwear, surgery and other offloading techniques for the prevention and healing of foot ulcers in patients with diabetes. Previous reviews have shown that sufficient evidence is available to support the use of non-removable offloading techniques to heal plantar forefoot ulcers,[11-13] but that more high-quality studies are needed to confirm promising effects of other offloading interventions to prevent and heal foot ulcers, in order to better inform clinicians and practitioners about effective treatment.[11] Over the last few years, several well-designed controlled studies have been performed to meet this goal.

In this guidance document, recommendations are given for each of the above-listed intervention groups, and include the rationale for how we arrived at a recommendation.[1] This rationale was based on available evidence from a systematic review of the literature, expert opinion where evidence is not available, and the consideration of benefits and harm, patients' values and preferences, and costs related to the intervention.

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[1] *Recommendations in this guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline (65). For much of the older data found in the systematic review underlying this guidance we could not calculate or assess for inconsistency, indirectness or imprecision, which are needed to fully assess the quality of evidence. Therefore, we decided to assess the quality of evidence on: the risk of bias of included studies, effect sizes, and expert opinion, and rate the quality of evidence as 'high', 'moderate', or 'low'. We assessed the strength of each recommendation as 'strong' or 'weak', based on the quality of evidence, balance between benefits and harms, patient values and preferences, and costs (resource utilization). The rationale behind each recommendation is described in this guidance.*

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Casting and prefabricated healing devices

Are casting or prefabricated offloading effective techniques to heal plantar foot ulcers in patients with diabetes?

Recommendation 1:

To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot-device interface.
(GRADE recommendation: strong, Quality of evidence: high)

Rationale 1:

Two high-quality systematic reviews and meta-analyses of randomized and non-randomized controlled trials indicate that the use of non-removable offloading devices (both TCC and walkers rendered irremovable) results in a significantly higher proportion of healed diabetic neuropathic plantar forefoot ulcers when compared to removable off-loading devices (including both walkers and footwear).[12,13] A Cochrane systematic review and meta-analysis included five RCTs[14-18] with a cumulative total of 230 patients and found a relative risk ratio of 1.17 (95%CI 1.01-1.36; p=0.04) for non-removable offloading to achieve healing compared to removable offloading.[12] Another systematic review and meta-analysis included 10 randomized and non-randomized clinical studies with a cumulative total of 524 patients[14-16,18-24] and showed a significantly higher relative risk ratio of 1.43 (95%CI 1.11-1.84, p=0.001) for non-removable offloading to achieve healing compared to removable offloading.[13] Based on two, relatively small RCTs,[17,25] there is evidence to suggest that a removable walker rendered irremovable is as effective as a TCC in healing neuropathic plantar forefoot ulcers (RR=1.06; 95%CI 0.88-1.27; p=0.31).[13] Therefore, there is no particular preference for a TCC or prefabricated non-removable knee-high device to heal plantar foot ulcers, as long as an appropriate foot device interface is maintained. We conclude that the quality of evidence is high.

Possible adverse effects of non-removable knee-high devices include ankle joint immobilization, reduced activity level, potential risk of falls, knee or hip complaints due to asymmetry in walking from the unilaterally increased sole height, and pressure ulcers due to poor casting or fitting.[15,26,27] Nevertheless, we consider the benefits of effective and expedited healing to outweigh such potential harm. Many patients may prefer not to use a non-removable knee-high device as it limits them in their daily life, for example with sleeping, bathing, or driving a

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car. Practitioners may also see several barriers to the application of non-removable offloading, as surveys and epidemiological studies show only limited use of the TCC in clinical practice.[28,29] Cost-effectiveness has not been assessed to date. One study showed, however, that, while only 6% of patients with a foot ulcer were treated with a TCC, the average cost of treatment of these patients was half that incurred by patients who were not treated with a TCC.[30]

Non-removable knee-high devices can be considered for healing ulcers that are mildly infected, i.e., under control with antibiotic treatment, and none to only small amounts of exudate.[31] Non-removable offloading is less suitable for heavily exudating ulcers or active infections that are not yet under control and that require frequent local care or inspection. Non-removable knee-high devices may also be considered in patients with mild peripheral arterial disease, i.e. present to a level that there is potential for wound healing.[31] If there is any doubt on potential for wound healing, do not use non-removable offloading. Do not use non-removable offloading when both mild infection and mild PAD is present.[31] With severely infected and/or severe ischemic foot ulcers, the infection and ischemia should first be resolved before offloading can be applied.

Recommendation 2:

When a non-removable knee-high device is contraindicated or not tolerated by the patient, consider offloading with a removable knee-high walker with an appropriate foot-device interface to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only when the patient can be expected to be adherent to wearing the device. (Weak; Moderate)

Rationale 2:

A systematic review and meta-analysis, including 10 randomized and non-randomized clinical studies and a cumulative total of 524 patients[14-16,18-24] showed significantly better healing for non-removable offloading compared to removable offloading (RR 1.43 (95%CI 1.11-1.84, p=0.001).[13] However, stratified by type of removable device, five RCTs14-16,18,22 found a trend but no statistically significant difference between non-removable knee-high off-loading devices and removable knee-high walkers (RR=1.23, 95%CI 0.96-1.58, p=0.085).[13] Based on the availability of five RCTs, and wide confidence interval around the point estimator of relative risk (suggesting inconsistency), we conclude that the quality of evidence is moderate.

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Possible adverse effects of knee-high removable devices include ankle joint immobilization, reduced activity level, potential risk of falls, or knee or hip complaints due to asymmetry in walking from the unilaterally increased sole height. Nevertheless, we consider the benefits of effective treatment to outweigh the potential harm. Patients may value and prefer the use of a removable knee-high offloading device, as it is more practical than non-removable offloading for activities such as bathing, sleeping and driving a car. However, the possibility of non-adherence should always be considered, as one study showed that patients with active ulcers who are prescribed with a removable walker wore their device only 28% of the steps that they took.[32] Practitioners may also prefer a removable walker over a TCC, since the former does not require a skilled technician to apply the device. Furthermore, wound care and inspection can take place at any time with a removable device, not only when devices are replaced such as with non-removable offloading. Costs are considered to be relatively high for many of the available removable knee-high walkers, but should always be considered with respect to efficacy in healing; cost-effectiveness has not been reported to date.

Additionally, removable walkers can be considered for healing:

- Heavily exudating plantar foot ulcers or ulcers with active mild infection that is not yet under control, which requires frequent local care or inspection.
- Plantar foot ulcers when there is mild PAD and some doubt regarding the potential for wound healing.
- Plantar foot ulcers when both a mild infection that is under control and mild PAD with potential for healing are present.

With severely infected or ischemic foot ulcers, the infection or ischemia should first be resolved before offloading can be applied.

Recommendation 3:

A knee-high device is contraindicated or cannot be tolerated by the patient, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only and when the patient can be expected to be adherent to wearing the shoes. (Weak; Low)

Rationale 3:

Several non-controlled studies show that 70% to 96% of plantar foot ulcers can be healed in a reasonable time frame (mean 34 -79 days) with ankle-high removable offloading shoes such as cast shoes, half shoes, and fore-

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foot offloading shoes.[33-37] These outcomes are comparable to those found with TCC. However, in the only controlled study on this topic, half shoes have shown to be inferior to the TCC.[15] The use of custom-made temporary shoes for healing relatively large and deep ulcers, some with mild infection, in neuropathic patients of which many had moderate PAD, was examined in one RCT at low risk of bias. The study found relatively low healing proportions, and equivalence in healing proportion and reduction in ulcer area between the temporary shoes and a TCC.[20] Based on the limited number of controlled studies, the quality of evidence is low.

The benefits of treatment with ankle-high offloading shoes compared to other ankle-high modalities such as conventional shoes will likely outweigh potential harm, but compared to knee-high devices the lower efficacy and/or longer healing times associated with such interventions poses a higher risk for infection and hospitalization. The traditional form of half-shoes, that only support the midfoot and heel,[36] are contra-indicated due to risk of midfoot fracture. Patients may prefer to use an ankle-high modality over a knee-high device to promote walking, and among ankle-high modalities likely prefer a comfortable cast shoe or custom-made temporary shoe over a half-shoe or forefoot offloading shoe, because the latter have a significant negative rocker outsole that may cause balance problems during gait. The cost of treatment is relatively low for forefoot offloading shoes and cast shoes, both requiring no replacement during treatment. Costs for custom-made temporary shoes are relatively higher; cost-effectiveness has not been reported.

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Therapeutic footwear

Is therapeutic footwear effective to prevent first or recurrent foot ulcers in patients with diabetes?

Recommendation 4:
To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside (Strong; Low).

Rationale 4:
No studies have been performed on the effect of walking barefoot, in socks, or in thin-soled standard slippers, on risk of foot ulceration. However, there are many large prospective studies that show that at-risk patients with diabetes have elevated levels of mechanical plantar pressure during barefoot walking, which are a significant independent risk factor for foot ulceration,[7,9] and should therefore be reduced. In addition, walking barefoot, in socks, or in thin-soled standard slippers provides only limited protection against thermal or external trauma.

Recommendation 5:
Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom made insoles, or toe orthosis. (Strong; Low)

Rationale 5:
One RCT with high risk of bias showed a positive effect of therapeutic footwear over no footwear prescription in at-risk patients, most of which had no ulcer history, to prevent ulcer incidence.[38] Another RCT with high risk of bias showed a clear trend, but no significant effect of shear-reducing insoles.[39] A third RCT at very low risk of bias showed that digital silicone orthoses can significantly reduce first ulcer incidence in at-risk patients with pre-ulcerative lesions.[40] Relative risk reduction for use of the intervention varied between and 69.8% and 92.9% in these studies, although the 95% confidence intervals show that effect may vary for individual patients.
There are no studies on the effect of therapeutic footwear on the prevention of non-plantar lesions. However, ill-fitting footwear has been identified as an important cause of non-plantar ulcers,[41] suggesting that properly fitting footwear can protect against ulceration. In properly fitting footwear, the shoe should not be either too tight or too loose. The inside of the shoe should be 1-2 cm longer than the foot. The internal width should equal the

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width of the foot at the metatarsal phalangeal joints (or the widest part of the foot), and the height should allow enough room for all the toes. Evaluate the fit with the patient in the standing position, preferably at the end of the day. Those patients with a foot deformity or a pre-ulcerative sign may need further adaptations to their footwear, which may include therapeutic footwear, custom-made insoles or a toe orthosis. Based on the small number of RCTs, on a wide range of interventions, the quality of evidence is low.

Little harm has been reported from (properly fitting) therapeutic footwear. Therefore the benefits likely outweigh the potential harm. We know little about adherence of patients to wearing therapeutic footwear before an ulcer has developed. Patients will likely value the role of therapeutic footwear to prevent ulcers, but they may still believe that their footwear is the cause if a foot ulcer occurs. Furthermore, anecdotally, many patients prefer not to wear 'bulky' custom-made shoes when they have not yet experienced a foot ulcer. The cost-effectiveness is unknown.

Recommendation 6:

To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking (i.e. 30% relief compared to plantar pressure in standard of care therapeutic footwear), and encourage the patient to wear this footwear (Strong; Moderate)

Rationale 6:

Two RCTs with very low risk of bias show that therapeutic footwear that has proven to effectively offload the foot can significantly reduce the risk for a recurrent plantar foot ulcer. One of the trials was specific to metatarsal head ulcers, and in the other trial the effect required adherence to wearing the footwear.[6,42] Effect sizes were large (46.1 – 63.6% relative risk reduction compared to standard of care therapeutic footwear) but 95% confidence intervals show that effect may vary across patients. These data confirm earlier findings in three RCTs with mixed methodological quality on the efficacy of therapeutic footwear (relative risk reductions compared to control condition: 52.5 – 70.2%).[38,39,43] One other RCT at low risk of bias assessed the effect of therapeutic insoles and showed no significant effect on ulcer recurrence compared to standard footwear (relative risk reduction 12%).[44] However, the latter study did not use insoles with proven efficacy in offloading plantar pressure. Based on the availability of several trials at very low or low risk of bias, some inconsistency in findings between trials, and large confidence intervals around effect size, we conclude that the quality of evidence is moderate.
The benefits of continuously wearing footwear with a proven offloading effect outweigh the potential harm, since

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few footwear-related complications are reported in these trials. Patients may value the use of therapeutic footwear to protect their feet against ulcer recurrence, but often patients do not wear the footwear, especially when at home.[45] Some patients may not know that their prescribed footwear should also be worn inside the house. Such patients should be correctly informed about the purpose and value of their therapeutic footwear and be motivated to continuously wear the footwear.[46] Other patients may prefer not to wear their therapeutic footwear at home because they find their shoes heavy, bulky, dirty, difficult to don and doff, or for religious reasons. In such cases, prescription of an additional pair of offloading footwear specifically for indoor use may be a useful solution, although evidence is currently lacking.[45] The costs of prescribing therapeutic footwear with demonstrated offloading effect may be quite high as it requires the measurement of barefoot or in-shoe plantar pressure for which equipment to date can be relatively expensive. However, these costs should always be regarded in association with the benefit for ulcer prevention; cost-effectiveness has not been studied to date but, in our opinion, footwear designed or evaluated using plantar pressure measurement will likely be cost-effective when it reduces risk of ulcer recurrence by 50%, as was found in most trials on this topic.

This recommendation is predicated on the availability of both therapeutic footwear and technology for pressure measurement. Not in all regions and clinical settings, however, plantar foot pressure can be measured. For these cases, we recommend to prescribe therapeutic footwear using available state-of-the-art scientific knowledge on footwear designs that effectively offload the foot.

Is therapeutic footwear effective to prevent first or recurrent foot ulcers in patients with diabetes?

Recommendation 7:

Do not prescribe, and instruct the patient with diabetes not to use, conventional or standard therapeutic shoes to heal a plantar foot ulcer (Strong; Low)

Rationale 7:

There are no studies that show the efficacy of conventional or standard therapeutic shoes to heal neuropathic plantar foot ulcers. In the few studies in which this footwear has been tested as comparison condition, the footwear proved inferior to other offloading devices.[19]

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Harm will outweigh the benefits for the use of conventional or standard therapeutic footwear for ulcer healing. Patients may prefer such shoes to knee-high offloading devices because they facilitate walking. Costs for conventional or standard therapeutic footwear are relatively low, but this footwear is not expected to be cost-effective in comparison to other commonly used offloading devices.

Recommendation 8:
Consider using shoe modifications, temporary footwear, toe spacers or orthoses to offload and heal a non-plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. The specific modality depends on the type and location of the foot ulcer. (Weak; Low)

Rationale 8:
There is no evidence available on how to treat non-plantar foot ulcers, even though such lesions often also need relief from mechanical stress. Depending on the location of the ulcer, various modalities can be considered, including shoe modifications, temporary footwear, toe spacers and orthoses. Temporary footwear does not have to be custom-made, but can consist of properly-fitting standard therapeutic footwear that prevents direct contact with the ulcer.

Based on expert opinion, we expect the benefits of the use of these modalities to outweigh any potential harm such as lesions caused by the footwear or orthoses. Patients will likely value the use of these modalities and prefer them for treatment of their non-plantar foot ulcers. Costs for applying these modalities are relatively low.

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Surgical offloading interventions

Is surgical offloading effective to prevent first or recurrent foot ulcers in patients with diabetes?

Recommendation 9:
Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar foot ulcer (Weak; Low)

Rationale 9:
One RCT with low risk of bias and several non-controlled studies show the positive effect of Achilles tendon lengthening (ATL), performed primarily to heal recalcitrant forefoot plantar ulcers, in preventing ulcer recurrence.[47-53] Relative risk reductions over conservative treatment were 75% and 52% at seven months and two years, respectively.[47] One small RCT with low risk of bias[54], two retrospective cohort studies with varying risk of bias,[55,56] and several non-controlled studies,[57-60] found efficacy of single or pan metatarsal head resections to prevent ulcer recurrence. The controlled studies showed relative risk reductions between 61.1% and 83.8% over conservative treatment. Two small retrospective cohort studies with high risk of bias and three non-controlled studies showed low ulcer recurrence rates after metatarsal-phalangeal or inter-phalangeal joint arthroplasty.[61-65] One of the cohort studies showed a relative risk reduction of 83.6% compared to conservative treatment. One retrospective cohort study on osteotomy showed a 60% but non-significant reduction in ulcer recurrence compared to conservative treatment, while one non-controlled study showed no ulcer recurrence after osteotomy.[66,67]

While effect sizes are often large, only few controlled studies per intervention show the efficacy of these surgical approaches. Furthermore, these surgical procedures apply to selected patients only: for all mentioned surgical procedures they apply to those patients that fail conservative treatment for an active foot ulcer and who are considered at very high risk if foot structure is not permanently changed. Furthermore, ATL applies only to patients with limited ankle dorsiflexion. Considering the small number of controlled studies and the often high risk of bias in the studies on surgical offloading, we conclude that the quality of evidence is low.

Possible complications and side effects of these surgical offloading techniques include infection, gait problems, acute Charcot neuro-osteoarthropathy, and transfer ulcers.[50,59,68] Risk of a heel ulcer after ATL was 13% in two years in one study that also showed a 34% increase in heel peak pressure.[47] In another study, risk for heel ulcers

was 15% at a median 12 months follow-up that also showed that the highest risk for heel ulcers (47%) was in patients with heel anaesthesia and significant dorsiflexion that was possible after ATL; these conditions therefore imply a contraindication.[50] Other studies report no, or only a small risk of heel ulceration from ATL.[51-53] Risk of transfer ulcers after single metatarsal head resection was 41% in an average 13.1 months in one study,[59] while two other studies did not report any transfer ulcers from this procedure at either six or 12 months follow-up.[55,56] In non-selected patients with diabetic neuropathy undergoing foot- and ankle surgery, post-operative surgical site infection developed in 9.5%.[69] Based on these outcomes, it is not clear if the benefits outweigh the potential harm. Patient value and preferences for these approaches are unknown, although we expect patients to value an intervention as high when it can prevent ulcers, but as low when it causes complications. The costs of surgical interventions are generally higher than for conservative treatment, although one study showed no difference in costs between metatarsal head resection and conservative treatment.[68] Cost-effectiveness is unknown.

Recommendation 10:

Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the toe. (Weak; Low)

Rationale 10:

Seven retrospective case series of percutaneous digital flexor tendon tenotomy performed in patients primarily to heal apex toe ulcers, reported a recurrence rate after healing between 0 and 20% over a mean follow-up between 11 and 36 months in a cumulative total 231 treated patients.[70-76] Four of the seven studies also reported on the effects of digital tenotomy of a toe where no ulcer was present at the time of the procedure. In a cumulative total of 58 patients with impending ulcers (i.e. callus on the tip of the toe) there was no reported ulcer occurrence in a mean 11 to 31 month follow-up.[72-74,76] While controlled studies on this topic are lacking, we consider this a promising procedure, to prevent both first and recurrent ulcers, in patients with pre-ulcerative lesions that fail conservative treatment. This is based on the low incidence rates found, our expert opinion, and results from healing studies. The quality of evidence is nevertheless low.

The possible benefits of digital flexor tenotomy likely outweigh the harm; very few complications have been reported. Patients who have pre-ulcerative lesions for which they have frequent conservative treatment that does not improve outcome may value and prefer treatment by flexor tenotomy. Furthermore, flexor tenotomy is easily performed in an outpatient setting, with no need for subsequent immobilization, and is not likely to negatively affect foot function. Costs and cost-effectiveness of this procedure have not been evaluated.

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Other offloading interventions

Are any other offloading techniques effective to prevent foot ulcers in patients with diabetes?

Recommendation 13:
If other forms of biomechanical relief are not available, consider using felted foam in combination with appropriate footwear to offload and heal a neuropathic foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. (Weak; Low)

Rationale 13:
Two RCTs with high risk of bias and one retrospective cohort study examined the effect of felted foam in ulcer healing. One RCT showed significantly shorter time to healing with felted foam worn in a post-operative shoe when compared to a pressure relief half-shoe used without the felted foam.[78] Another RCT showed no difference in healing proportion or time to healing between felt fitted to the foot compared with felt fitted to temporary therapeutic footwear.[79] Felted foam worn in a surgical shoe, a healing shoe, or a walking splint was reported to be as effective as a TCC in both healing proportion and time to healing.[35] Based on the lack of well-designed controlled studies, and the difficulty in determining the added effect of felted foam in the studies performed, the quality of evidence is low.

Any benefit found with the use of felted foam will likely outweigh the harm, since studies of felted foam have reported no complications. Patients will likely value and prefer the use of felted foam as an easy to use, non-limiting modality. The costs of felted-foam are relatively low, but it does require frequent replacement, either by the patient, a relative, or a home-care nurse. Based on the evidence from the studies performed, felted foam should only be used in addition to appropriate footwear, walkers or cast, and not as a single treatment modality.

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Key controversies

1. Many clinical studies on offloading do not directly measure the degree to which offloading has been achieved by the intervention. However, such measurements not only improve our understanding of the role of off-loading in prevention and healing, but also improve outcome.

2. To effectively heal plantar forefoot ulcers, the TCC is no longer necessarily the gold standard treatment option.[12,13] Prefabricated removable walkers that are rendered irremovable have been shown to be as effective as the TCC.[13] This changes the traditional view on offloading, in which the main comparison was TCC versus any other device, but has now changed in non-removable versus removable offloading. This has positive implications for those settings where casting technicians are not available or where personnel are not specifically trained. In these settings, reliance on the correct use of prefabricated methods for offloading seems appropriate.

3. Offloading studies have focused almost exclusively on the treatment of non-complicated neuropathic plantar forefoot ulcers. Little to no data is available on the value of offloading in healing complicated plantar foot ulcers, midfoot and heel ulcers, or non-plantar ulcers, even though these ulcers are now more common in specialized settings.[1,31] Complicated ulcers require adjunctive treatment to reduce the infection and the ischemia, before offloading is initiated or during offloading when complications are only mild. High-quality studies on offloading ulcers other than the non-complicated neuropathic plantar forefoot ulcer are urgently needed.

4. Adherence to an intervention is crucial in preventing and healing foot ulcers. It is consistently reported that those who do not adhere to an intervention present with worse clinical outcomes. A stronger focus is required, both in research and in clinical practice, on the measurement and improvement of treatment adherence.

5. Surgical offloading has primarily been applied to heal foot ulcers in selected patients, and only secondarily to prevent ulcer recurrence. It is therefore interesting that surgical offloading, when compared to conservative treatment, has been shown to be more effective in preventing recurrence than in healing foot ulcers. This controversy between application and efficacy needs more attention and may shift the focus of surgical intervention to being more an approach that is valuable for prevention than for healing.
6. Those at-risk patients who have not yet developed a foot ulcer have received little attention in footwear and

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offloading studies. Few interventions have been adequately investigated or are widely accepted in clinical practice. In several cases, benefits in preventing a first foot ulcer may not outweigh possible harm or costs, as large groups of patients will be targeted while event rate is relatively low. These patient categories, however, should be carefully evaluated, before definitive conclusions can be drawn.

7. Costs and cost-effectiveness have also received very little attention in studies on footwear and offloading, despite the fact that reimbursement through insured care is more and more dependent on proven cost-effectiveness. More attention is warranted in view of the continuing pressure of health care cost-containment.

8. The majority of interventions discussed are from studies from more economically developed countries with relatively temperate climates. While some of these interventions are broadly applicable, there is a need for more specific guidance on approaches to ulcer prevention and healing in these lower income regions where climate and/or resources may be a factor in adherence to, or efficacy of, treatment.

Conflict of interest

PRC owns stock in DIApedia and is an inventor on US patents 6,610,897 6,720,470 and 7,206,718 that describe a load relieving dressing and a method of insole manufacture for offloading diabetic feet.
SB, RvD, DGA, JL, CC: none declared

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Glossary

B

Bespoke shoe: British English synonym for Custom-made shoe (see below)

C

Cast shoe: a removable plaster or fibreglass cast that extends to just below or at the ankle joint, moulded around the shape of the foot with total contact of the entire plantar surface. Examples are Mabal cast shoe, Ransart boot or Scotch-cast boot.

Conventional shoe: "off-the-shelf" mass-produced shoe without any intended therapeutic effect.

Custom-made insole: accommodative insole made to the contours of the individual foot of the patient often in a multi-layer construction. May also incorporate other modifications such a Metatarsal pad or Metatarsal bar.

Custom-made shoe: a unique, usually hand-made, shoe built on a positive model of the patient's foot to accommodate deformity and relieve pressure over at-risk sites on the plantar and dorsal surfaces of the foot. See also Bespoke shoe and Orthopaedic shoe.

Custom-made temporary shoe: a unique, usually hand-made, shoe that is manufactured in a short time frame and is used temporarily to treat a foot ulcer. The shoe is built on a positive model of the patient's foot to accommodate deformity and relieve pressure over the ulcer site on the plantar surface of the foot.

Customized insole: loosely used term in American English to denote a pre-fabricated insole to which some minor modifications specific to the patient's foot may have been made. This term is not synonymous with Custom-made insole.

D

Depth inlay shoe: American English synonym for Extra-depth shoe.

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Depth shoe: American English synonym for Extra-depth shoe.

E

Extra-depth shoe: shoe constructed with additional depth and volume in order to accommodate deformity such as claw/hammer toes and/or to allow for space for a thick insole. Usually a minimum of 5 millimetres (~3/16") depth is added compared to a conventional shoe. Even greater depth is sometimes provided in shoes that are referred to as double depth or super extra-depth. See also Depth Inlay shoe and Depth Shoe.

F

Felted foam: a fibrous, unwoven material backed by foam with absorbing and cushioning characteristics

Forefoot offloading shoe: prefabricated shoe especially designed for relieving forefoot locations on the foot. The footwear has a specific shape with a wedge design and the outsole portion missing in the forefoot. These shoes are usually worn unilaterally.

H

Half shoe: prefabricated shoe designed to offload the forefoot. The anterior part of the shoe is cut out leaving the heel and the midfoot as the only weight-bearing surfaces.

Healing shoe/sandal: specially designed sandals with insoles that reduce pressure.

Heel-relief shoe: shoe designed to offload the heel. The heel part is missing from the footwear and its sole arrangement is constructed in such a way that the heel is not loaded when walking.

I

In-shoe orthosis: term used for devices put inside the shoe to achieve some alteration in the function of the foot.

In-shoe orthotics: term sometimes loosely used for devices put inside a shoe to achieve some alteration in function. Correct plural of orthosis is actually orthoses.

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L

Liner: American English synonym for insole.

M

Mabal cast shoe: removable fibreglass combi-cast shoe existing 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.

Metatarsal pad: Small pad placed behind the metatarsal head to relieve focal pressure and transfer load more proximally.

Metatarsal bar: bar extending across part of or the entire forefoot placed behind the metatarsal heads to relieve focal pressures and transfer load more proximally.

N

Non-removable (cast) walker: Same as removable (cast) boot/walker but then with a layer(s) of fibreglass cast material circumferentially wrapped around it rendering it irremovable (also known as “instant total contact cast”)

O

Orthopaedic shoe: synonym for Custom-made shoe (see above)

P

Post-operative shoe: prefabricated shoe with roomy and soft upper worn after an operation to the foot.

Pre-fabricated insole: an “off-the-shelf” flat or contoured insole made without reference to the shape of the patient’s foot.

R

Ransart boot: removable fibreglass combi-cast shoe extending to just below the ankle, existing of minimal pad-

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ding and moulded to the shape of the foot with total contact of the entire plantar surface. A window is cut over the ulcer area.

Removable (cast) boot/walker: prefabricated removable knee-high boot with a rocker or roller outsole configuration, padded interior, and an insertable and adjustable insole which may be total contact.

Rocker shoe: Shoe with rigid outsole designed and a sharp transition on the outsole. The shoe rocks forward in the late support phase to allow walking without extension of the metatarsal-phalangeal joints.

Roller shoe: Shoe with rigid outsole similar to the rocker shoe, but with a contoured outsole to provide a smoother transition during walking

S

Scotch-cast boot: a removable well-padded cast cut away at the ankle. Windows are cut over the ulcers if needed. For large heel ulcers, a removable heel cap of fibreglass is added. The boot is worn with a cast sandal to increase patient mobility.

Shoe insert: loosely used American English synonym for insole or in-shoe orthosis.

Shoe modification: modification to an existing shoe with an intended therapeutic effect, e.g. pressure relief.

Standard therapeutic shoe: pre-fabricated form of Therapeutic shoe, without any customization to the patient's foot.

T

Temporary shoe: Pre-fabricated shoe that is used temporarily to treat a foot ulcer.

Therapeutic Shoe: Generic term for footwear designed to allow some form of treatment to be applied to the foot that cannot be applied by or in a conventional shoe. Extra depth shoes, custom-made shoes, etc. are all examples of therapeutic shoes. (Greek therapeutikos, from therapeuein to attend, treat).

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Toe orthosis: an in-shoe orthosis to achieve some alteration in the function of the toe.

Total contact cast: a 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 to facilitate walking.

W

Windowed cast: same a total contact cast but then with a window cut out at the site of an ulcer to facilitate wound assessment and treatment in-between cast replacements

IWGDF Guidance on the diagnosis, prognosis and management of peripheral artery disease in patients with foot ulcers in diabetes

Prepared by the IWGDF Working Group on Peripheral Artery Disease

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