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SUPPLEMENT ARTICLE

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Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2019 update)

Sicco A. Bus[1] | David G. Armstrong[2] | Catherine Gooday[3,4] | Gustav Jarl[5,6] | Carlo F. Caravaggi[7,8] | Vijay Viswanathan[9] | Peter A. Lazzarini[10,11]

on behalf of the International Working Grroup on the Diabetic Foot (IWGDF)

[1]Amsterdam UMC, University of Amsterdam, Department of Rehabilitation Medicine, Amsterdam Movement Sciences, Amsterdam, The Netherlands

[2]Southwestern Academic Limb Salvage Alliance (SALSA), Department of Surgery, Keck School of Medicine of University of Southern California (USC), Los Angeles, California

[3]Elsie Bertram Diabetes Centre, Norfolk and Norwich University Hospitals, Norwich, UK

[4]School of Health Sciences, University of East Anglia, Norwich, UK

[5]Department of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

[6]University Health Care Research Center, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

[7]Diabetic Foot Department, IRCCS Multimedica Group, Milan, Italy

[8]University Vita-Salute San Raffaele, Milan, Italy

[9]MV Hospital for Diabetes, Chennai, India

[10]School of Public Health and Social Work, Queensland University of Technology, Brisbane, Queensland, Australia

[11]Allied Health Research Collaborative, The Prince Charles Hospital, Brisbane, Queensland, Australia

Correspondence
S.A. Bus, Amsterdam UMC, University of Amsterdam, Department of Rehabilitation Medicine, Amsterdam Movement Sciences, Amsterdam, The Netherlands.
Email: s.a.bus@amsterdamumc.nl

Abstract

The International Working Group on the Diabetic Foot (IWGDF) has published evidence-based guidelines on the prevention and management of diabetic foot disease since 1999. This guideline is on the use of offloading interventions to promote the healing of foot ulcers in people with diabetes and updates the previous IWGDF guideline.

We followed the GRADE methodology to devise clinical questions and critically important outcomes in the PICO format, to conduct a systematic review of the medical-scientific literature, and to write recommendations and their rationale. The recommendations are based on the quality of evidence found in the systematic review, expert opinion where evidence was not available, and a weighing of the benefits and harms, patient preferences, feasibility and applicability, and costs related to the intervention.

For healing a neuropathic plantar forefoot or midfoot ulcer in a person with diabetes, we recommend that a nonremovable knee-high offloading device is the first choice of offloading treatment. A removable knee-high and removable ankle-high offloading device are to be considered as the second- and third-choice offloading treatment, respectively, if contraindications or patient intolerance to nonremovable offloading exist. Appropriately, fitting footwear combined with felted foam can be considered as the fourth-choice offloading treatment. If non-surgical offloading fails, we recommend to consider surgical offloading interventions for healing metatarsal head and digital ulcers. We have added new recommendations for the use of offloading treatment for healing ulcers that are complicated with infection or ischaemia and for healing plantar heel ulcers.

Offloading is arguably the most important of multiple interventions needed to heal a neuropathic plantar foot ulcer in a person with diabetes. Following these recommendations will help health care professionals and teams provide better care for diabetic patients who have a foot ulcer and are at risk for infection, hospitalization, and amputation.

KEYWORDS

cast, diabetic foot, foot ulcer, footwear, guidelines, offloading, surgery

International Working Group on the Diabetic Foot (IWGDF); www.iwgdfguidelines.org

LIST OF RECOMMENDATIONS

1. (a) 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 (GRADE strength of recommendation: Strong; Quality of evidence: High).
   (b) 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 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 nonremovable 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).
4. (a) 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 abovementioned offloading devices is available (Strong; Moderate).
   (b) 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).
7. (a) 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).
   (b) 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).
   (c) 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).

1 | INTRODUCTION

Diabetes-related foot ulceration (DFU) results in a large global morbidity, mortality, and cost burden.[1-5] DFU annually affects around 26 million people worldwide.[2,4] Without appropriate care, these foot ulcers can lead to hospitalization, amputation, and death.[1-5] Thus, healing of DFU is of paramount global importance.[1-5]

Peripheral neuropathy affects around half of all people with diabetes and leads to loss of protective sensation in the feet.[2-4] Elevated levels of mechanical stress in the presence of loss of protective sensation are one of the most common causes of DFU.[2,6-8] Mechanical stress is composed of plantar pressures and shear accumulated during repetitive cycles of weight-bearing activity.[2,6-8] Peripheral neuropathy can also lead to further changes in gait, foot deformity, and soft tissue, all of which can further elevate mechanical stress.[7-9] Thus, the combination of loss of protective sensation and elevated mechanical stress leads to tissue damage and DFU.[2,6,10] Once a DFU forms, healing is chronically delayed if the area is not effectively offloaded.[2,6,10]

Multiple interventions are typically required to effectively heal a DFU, including local wound management, infection management, revascularization, and pressure offloading.[11,12] The first three of those interventions are covered in other parts of the International Working Group of the Diabetic Foot (IWGDF) Guidelines.[12-15] In people with neuropathic DFUs, pressure offloading is arguably the most important of these interventions.[10-12] There is a long standing clinical tradition of using different offloading devices, footwear, surgery, and other offloading interventions to heal DFUs.[6,10,16-18] Previous IWGDF Guidelines have shown that sufficient evidence is available to support the use of nonremovable knee-high offloading devices to heal plantar forefoot ulcers, over all other offloading interventions.[10,12,19] It also identified that more high-quality studies are needed to confirm the promising effects of other offloading interventions to heal DFUs, in order to better inform practitioners about effective treatments.[10,19] Over the last few years, several well-designed controlled studies have been performed in this field that add to the evidence base for offloading foot ulcers in patients with diabetes.[20-23]

This guideline aims to update the previous IWGDF guideline on footwear and offloading.[19] However, unlike the previous guideline, this guideline no longer includes footwear and offloading for the prevention of foot ulcers; it focuses only on offloading for the management of foot ulcers. Footwear and offloading for the prevention of foot ulcers are now covered by the IWGDF guideline on prevention.[24] Other IWGDF guidelines in this series include those on peripheral artery disease, infection, wound healing, and ulcer classification.[25-28]

2 | METHODS

In this guideline, we have followed the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) methodology, which is structured around clinical questions in the PICO format (Patient-Intervention-Comparison-Outcome), systematic searches and assessment of the available evidence, followed by developing recommendations and their rationale.[29,30]

First, a multidisciplinary working group of independent experts (the authors of this guideline) was installed by the IWGDF Editorial Board. The members of the working group devised the clinical questions, which were revised after consultation with external experts from various geographical regions and the IWGDF Editorial Board. The aim was to ensure the relevance of the questions for clinicians and other health care professionals in providing useful information on offloading interventions to heal foot ulcers in people with diabetes. We also formulated what we considered critically important outcomes relevant for daily care, using the set of outcomes defined by Jeffcoate et al[11] as a reference guide.

Second, we systematically reviewed the literature to address the agreed upon clinical questions. For each assessable outcome, we graded the quality of evidence based on the risk of bias of included studies, effect sizes, presence of inconsistency, and evidence of publication bias (the latter where appropriate). We then rated the quality of evidence as "high," "moderate," or "low." The systematic review supporting this guideline is published separately.[31]

Third, we formulated recommendations to address each clinical question. We aimed to be clear, specific, and unambiguous on what we recommend, for which persons, and under what circumstances. Using the GRADE system, we provided the rationale for how we arrived at each recommendation, based on the evidence from our systematic review,[31] expert opinion where evidence was not available, and a careful weighing of the benefits and harms, patient preferences, and financial costs (resource utilization) related to the intervention or diagnostic method.[29,30] Based on these factors, we graded the strength of each recommendation as "strong" or "weak" and for or against a particular intervention or diagnostic method. All our recommendations (with their rationales) were reviewed by the same international experts who reviewed the clinical questions, as well as by the members of the IWGDF Editorial Board.

We refer those seeking a more detailed description on the methods for developing and writing these guidelines to the "IWGDF Guidelines development and methodology" document.[32]

3 | RECOMMENDATIONS

A diagrammatic overview of the recommended offloading treatment approach to heal a foot ulcer in a person with diabetes can be found in Figure 1.

In this guideline, many different offloading interventions are mentioned. They are discussed according to the following categories: offloading devices, footwear, other offloading techniques, and surgical offloading techniques. We refer to the glossary for a definition and description of each of these offloading interventions and categories. Furthermore, many of the offloading devices and interventions recommended require specific training, skills, and experience to apply properly. As these specific skills and training are not described in the studies performed and may differ between countries, we suggest that the person applying the offloading should be a properly trained health care professional who according to their national or regional standards has the knowledge, expertise, and skills necessary to manage patients with a DFU.

3.1 | What's new?

We have made several changes to the recommendations included in this updated 2019 IWGDF offloading guideline when compared with the previous IWGDF offloading guideline.[19] The main changes are the following:

- Removed any recommendations on the prevention of foot ulcers (these are now covered in the updated 2019 IWGDF prevention guideline[24]).
- Outlined clearly the first, second, third, and fourth choice of offloading treatment to heal a neuropathic plantar forefoot or midfoot ulcer.
- Added one new recommendation on considerations for choosing between either a total contact cast or nonremovable knee-high walker.
- Added three new recommendations on offloading treatments for people with neuropathic plantar forefoot ulcers that are complicated by infection or ischaemia.
- Added a new recommendation on offloading treatments for people with neuropathic plantar heel ulcers.

3.2 | Offloading devices

PICO 1: In people with a plantar DFU, are nonremovable offloading devices compared with removable offloading devices effective to heal the DFU?

Recommendation 1a

In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, use a nonremovable knee-high offloading device with an

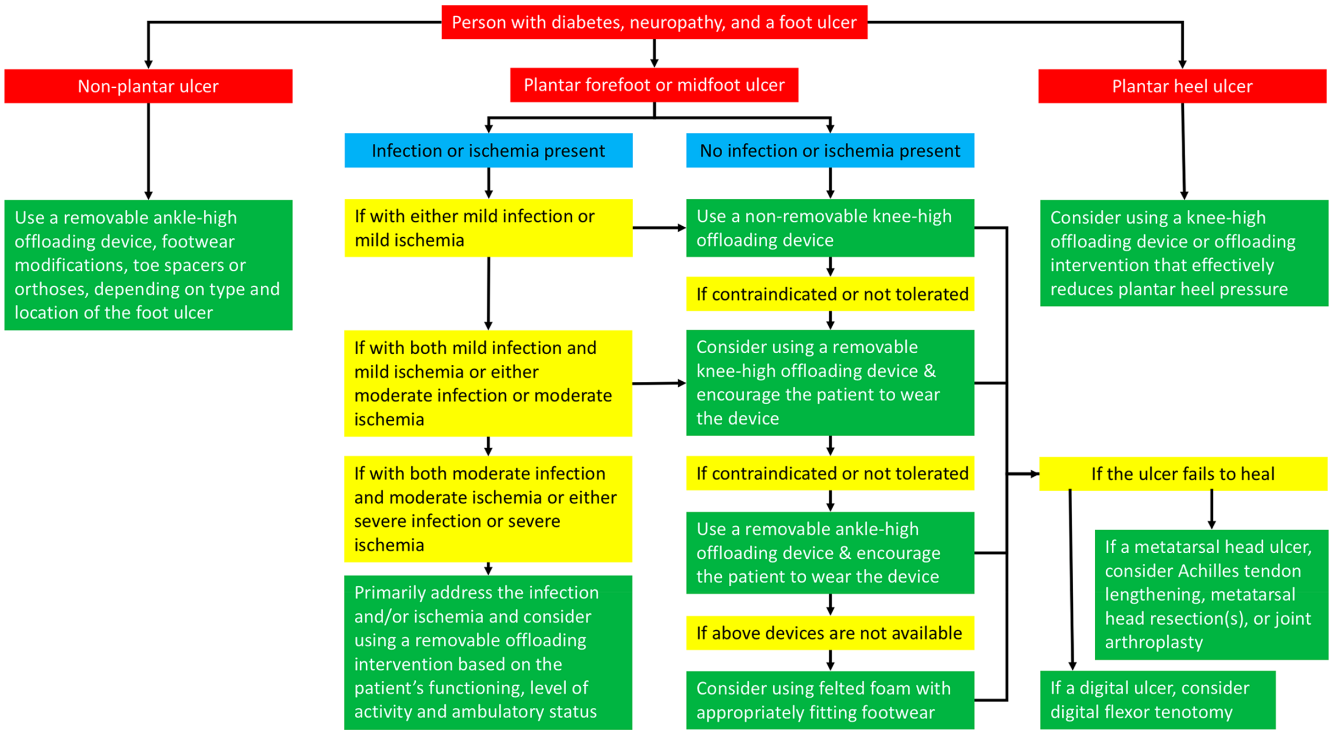

FIGURE 1 Flow diagram on the recommended offloading treatment for a person with diabetes and a foot ulcer

appropriate foot-device interface as the first choice of offloading treatment to promote healing of the ulcer (GRADE strength of recommendation: Strong; Quality of evidence: High).

Rationale

Nonremovable knee-high offloading devices consist of total contact casts (TCCs) and nonremovable walkers.[19] TCCs are custom-made, knee-high, nonremovable casts, and nonremovable walkers are prefabricated, knee-high, removable walkers rendered irremovable by applying a layer of cast or tie wrap around the device. These walkers may involve a modular insole system or have an (custom) insole added. In any case, an appropriate foot-device interface is required, meaning that peak pressures are adequately distributed and reduced at the ulcer location. Nonremovable offloading devices offer several benefits for healing a DFU over other offloading interventions, including better redistribution of pressure over the foot and lower leg and enforced adherence.[6,10,19,33] These factors play an important role in the healing of foot ulcers with nonremovable offloading.

Our updated systematic review[31] identified five high-quality meta-analyses of controlled trials on this topic,[33-37] with much overlap present between the meta-analyses on the trials included. All found that nonremovable offloading devices result in significantly improved healing outcomes for neuropathic plantar forefoot ulcers when compared with removable devices (removable offloading devices or footwear).[33-37] For those meta-analyses reporting relative risks, they found nonremovable offloading devices were 17% to 43% more likely than removable devices to heal a neuropathic plantar forefoot ulcer ($P < 0.05$).[34,36,37] For those reporting time-to-healing, they found nonremovable offloading devices healed ulcers 8 to 12 days quicker than removable devices ($P < 0.05$).[33,35] We conclude that nonremovable knee-high offloading devices have clear healing benefits over removable devices. The quality of evidence is rated as high.

Possible adverse effects of nonremovable offloading devices include muscle weakness, falls, new ulcers because of poor fitting, and knee or hip complaints because of the acquired limb-length discrepancy when wearing the device.[38-40] One may consider a shoe raise for the contralateral limb to minimize this acquired limb-length discrepancy. In most randomized controlled trials (RCT), the wide variation in type of adverse events, relatively small sample sizes, and low incidence of reported events prevented statistical testing between nonremovable and removable devices.[22,23,38,41-43] However, two meta-analyses reported no differences in skin maceration or treatment discontinuation (combination of adverse events, voluntary withdrawal, or losses to follow-up).[34,36] Additionally, six RCTs described low overall incidences (0%-20%) of adverse events, with no differences evident between nonremovable and removable devices for these events, including falls, maceration, abrasions, new ulcers, infections, and hospitalizations.[22,23,38,41-43] Nevertheless, clinicians and other health care providers should still be aware of these adverse events. We conclude nonremovable and removable offloading devices have similar low incidences of harm.

Many patients are thought to not prefer nonremovable knee-high offloading devices as they limit daily life activities, such as walking, sleeping, bathing, or driving a car.[34] Two RCTs reported on patient preferences with one reporting lower patient satisfaction with nonremovable compared with removable offloading devices[23] and the

other reporting no differences in patient satisfaction or comfort.[43] One large health technology assessment reported on qualitative interviews with 16 patients with DFU who were familiar with a variety of offloading devices.[34] They found that patients rated nonremovable offloading devices as preferable after they understood the healing benefits of nonremovable devices, even though they rated removable offloading devices as more comfortable, allowing greater freedom and mobility.[34] Practitioners may not prefer some nonremovable offloading, as surveys and epidemiological studies show low use of TCCs in clinical practice, but similar (and moderate) use of nonremovable and removable walkers.[16-18,44] We conclude that nonremovable and removable offloading devices may be equally preferred by both patients and clinicians.

Two RCTs reported on costs with one finding one-off device/material costs were higher for nonremovable and removable walkers than for TCCs,[38] and the other finding that TCCs and nonremovable walkers were less expensive over the course of treatment than removable walkers.[23] One large health technology assessment study systematically reviewed the literature and found no papers on economic evaluations of nonremovable offloading devices.[34] The authors then performed their own cost-effectiveness analysis, using existing literature and expert opinion, which showed that the cost per patient for 3 months of treatment (including all device/materials, dressings, consultations, labour, complication costs, etc.) was lowest for nonremovable walkers ($876) and TCCs ($1137), compared with removable walkers ($1629) and therapeutic footwear ($1934).[34] They concluded that nonremovable walkers and TCCs were superior to the other offloading interventions because they were both less expensive and more effective than removable walkers and therapeutic footwear. They also performed a cost-utility analysis that also showed that the cost per patient for 6 months of treatment (including all treatment costs and heath gains from ulcers healed and quality of life) was again lowest for nonremovable walkers ($2431) and TCCs ($2924), compared with removable walkers ($4005) and therapeutic footwear ($4940).[34] We conclude nonremovable offloading devices to be more cost-effective than removable offloading devices.

Contraindications for the use of nonremovable knee-high offloading devices, based predominantly on expert opinion, include presence of both mild infection and mild ischaemia, moderate-to-severe infection, moderate-to-severe ischaemia, or heavily exudating ulcers.[34-36,39,45] We refer to the IWGDF infection and PAD guidelines and the IWGDF definitions and criteria document for definitions on infection and ischaemia.[27,28,46] We identified no RCTs in this field that have included participants with these conditions, seemingly for safety reasons. However, we did identify controlled and noncontrolled studies that indicate no additional adverse events in people with mild infection or mild ischaemia.[39,45,47-51] One low-quality systematic review investigating mostly noncontrolled studies of TCC use in people with ischaemia recommended an ankle brachial index threshold of >0.55 for safe use of a TCC.[52] The use of nonremovable knee-high offloading devices may also induce an increased risk of falls with several studies reporting abnormal gait changes and imbalance in people with DFU wearing knee-high offloading devices.[53-55] However, in the aforementioned RCTs, there was no increase in reported falls-related adverse events in those wearing nonremovable knee-high offloading devices.[22,23,38,41-43] Further, studies investigating ankle foot orthoses, devices that share functional similarities to knee-high offloading devices, have shown ankle foot orthoses may help to improve balance and reduce falls in older people with neuropathy.[56,57] Future studies should specifically investigate the effect of knee-high offloading devices on risk of falls, and we suggest falls risk assessment should be done on a patient-by-patient basis.

In summary, the quality of the evidence from the meta-analyses performed was high, even though the quality of evidence from individual RCTs varied. All meta-analyses favoured the use of nonremovable knee-high over removable offloading to heal neuropathic plantar forefoot ulcers without infection or ischaemia present. These benefits outweigh the low incidence of harm, and with positive cost-effectiveness and mixed patient preference for the use of nonremovable over removable offloading devices, we grade this recommendation as strong. We refer to Recommendations 7a, 7b, and 7c for DFU that are infected or where ischaemia is present.

PICO 2: In people with a plantar DFU, are TCC compared with other nonremovable knee-high offloading devices effective to heal the DFU?

Recommendation 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 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).

Rationale

The TCC has been considered for decades the gold standard offloading intervention to heal a neuropathic plantar forefoot ulcer.[19,58] Our previous guideline broadened the recommendation to a nonremovable offloading device[19] to include both a TCC and a prefabricated removable knee-high walker rendered nonremovable with an appropriate foot-device interface. However, the previous guideline did not provide a recommendation on which one is preferable to use.[19]

Our updated systematic review[31] identified one high-quality meta-analysis on this topic[34] that included three high-quality RCTs.[23,59,60] The meta-analysis found no difference in ulcers healed using TCCs and nonremovable walkers ($P = 0.82$).[34] Another low-quality RCT also found no significant difference between a TCC and nonremovable knee-high walker for ulcers healed ($P = 0.99$) or time-to-healing ($P = 0.77$).[61] However, none of these four RCTs was based on a sample size calculation for equivalence.[59] Thus, the non-significant results of the individual RCTs may reflect low statistical power to detect differences, although the meta-analysis should have had sufficient power. We conclude that TCCs and nonremovable knee-high walkers are equally effective to heal DFUs.

As healing outcomes were similar, we analysed effects on the surrogate outcomes of plantar pressures and weight-bearing activity.[11] One RCT found a significantly greater plantar pressure reduction from barefoot pressure baselines in a knee-high walker compared with a TCC at the ulcer site (91% vs 80%), the forefoot (92% vs 84%), and midfoot (77% vs 63%) (all, $P < 0.05$), but no difference in the heel ($P = 0.11$).[62] However, several noncontrolled cross-sectional studies found no significant difference in plantar pressure reduction from standard footwear baselines in knee-high walkers compared with TCCs at the ulcer site, hallux, and forefoot.[63-66] We found no controlled studies investigating weight-bearing activity. We consider TCCs and nonremovable knee-high walkers to have similar effects on reducing plantar pressures.

Three high-quality RCTs reported adverse events for TCCs and nonremovable knee-high walkers and found no significant differences ($P > 0.05$).[23,59,60] Additionally, one meta-analysis found no significant difference for treatment discontinuation between these two devices ($P = 0.52$).[34] While the low numbers of adverse events and treatment discontinuations may have resulted in low power to detect differences, we consider these devices to have similarly low levels of harm. The same RCTs reported on patient preferences. One reported higher patient satisfaction with a nonremovable knee-high walker than with a TCC ($P < 0.05$),[60] while another reported no differences ($P > 0.05$).[23] Two of these RCTs also found that it took a significantly longer time to apply and remove a TCC than a nonremovable knee-high walker (by up to 14 min, $P < 0.01$).[59,60] We conclude that patient and practitioner preference for either device is mixed.

Four RCTs reported on the costs of using a TCC or nonremovable knee-high walker. One low-quality RCT reported that the one-off device/material costs for a TCC were lower than for a nonremovable offloading device ($20 vs $35, $P < 0.01$).[61] Three other, high-quality, RCTs reported that treatment costs were lower for nonremovable knee-high walkers than for TCCs.[23,59,60] One reported that device/material costs were lower ($158 vs $211, P = not reported),[59] another that all offloading treatment costs (ie, device/materials, cast changes, dressings, and cast technician salary) were significantly lower ($162 vs $727, $P < 0.001$),[60] and the third that average costs per day of treatment were significantly lower with a nonremovable walker than with a TCC (€83 vs €243, $P < 0.05$).[23] The cost-effectiveness analysis of a health technology assessment showed that the cost per patient for 3 months treatment was lower per patient for a nonremovable walker than for a TCC ($876 vs $1137).[34] When the costs and healing probabilities were modelled over 1000 patients with a DFU, they reported the TCC would heal 15 more ulcers (741 vs 726), but cost $260 420 more than the nonremovable knee-high walker ($1.137 vs $0.876 million). Thus, from a population-based perspective, they suggest that for each additional DFU healed using a TCC compared with using a nonremovable walker would cost a service $17 923, and therefore would not be more cost-effective in most services.[34] The same study found in a cost-utility analysis that the cost per patient for 6 months treatment were lower for a nonremovable walker than for a TCC ($2431 vs $2924).[34] We conclude that nonremovable walkers are generally more cost-effective than TCCs.

In summary, based on one high-quality meta-analysis of three high-quality RCT's showing consistent results for healing between the TCC and nonremovable knee-high walkers, and with a need for larger trials to test for equivalence, we rate the quality of evidence as moderate. Additionally, considering the equivalence in plantar pressure benefits and adverse events, and slight preference and lower costs for a nonremovable knee-high walker, we grade this recommendation as strong. However, we recommend to base the choice for either a TCC or a nonremovable knee-high walker on availability of the device/materials (ie, resources), skills of available cast technicians, appropriateness of the device to fit the level of any foot deformity (ie, a TCC with a severely deformed foot), and patient preferences.

PICO 3: In people with a plantar DFU, are removable knee-high offloading devices compared with other removable offloading devices effective to heal the DFU?

Recommendation 2

In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for whom a nonremovable 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).

Rationale

There are circumstances when a nonremovable knee-high offloading device is contraindicated (see rationale for Recommendation 1) or cannot be tolerated by the patient. Intolerance by the patient can include refusal to wear the device or the patient's circumstances do not support its use, such as unable to use the device as part of the patient's job. A removable knee-high offloading device may be a solution to these conditions.[19] A removable knee-high device redistributes peak pressures in a similar fashion as a nonremovable knee-high device,[6,10,19,33] although one study showed higher peak pressures during walking after a TCC was bivalved and made removable.[66] A removable knee-high device also redistributes pressure more effectively than a removable ankle-high offloading device (such as ankle-high walker, forefoot offloading shoes, half shoes, cast shoes, or postoperative sandal).[6,10,19,33]

Our systematic review[31] identified one high-quality meta-analysis,[34] that included two low-quality RCTs,[38,43] and found no difference in the proportion of plantar forefoot ulcers healed between removable knee- and ankle-high offloading devices (healing sandal or half shoe) ($P = 0.20$).[34] A more recent high-quality RCT also found no difference in plantar forefoot ulcers healed between a removable knee-high device (bivalved TCC) and either a removable ankle-high cast shoe or forefoot offloading shoe, at either 12 weeks ($P = 0.703$) or 20 weeks ($P = 0.305$).[20] However, the authors noted the removable knee-high device group had significantly more deep ulcers (University

of Texas grade 2) than both ankle-high device groups at baseline ($P < 0.05$).[20] None of the RCTs conducted were sufficiently powered for equivalence. We conclude from the current evidence available that removable knee- and ankle-high offloading devices have comparable effects on healing neuropathic plantar DFUs.

As healing outcomes were comparable between devices, we assessed surrogate measures.[11] One high-quality RCT[20] found a removable knee-high device (bivalved TCC) showed greater plantar pressure reductions from standard footwear baseline levels at the ulcer site than a removable ankle-high cast shoe or forefoot offloading shoe (67% vs 47% vs 26%, respectively, $P = 0.029$).[20] Several cross-sectional studies also found that removable knee-high devices show greater forefoot plantar pressure reduction than removable ankle-high devices.[53,54,64-67] Three RCTs investigated weight-bearing activity. One high-quality RCT found no differences in average daily step count between a removable knee-high device (bivalved TCC) and removable ankle-high cast shoe or forefoot offloading shoe device (4150 vs 3514 vs 4447, respectively, $P = 0.71$),[20] but it should be noted the study was not powered for this outcome. Another low-quality RCT found a large but non-significant reduction in daily steps in a removable knee-high device compared with a removable ankle-high half shoe (768 vs 1462 steps, $P = 0.15$).[38] A third low-quality RCT found significant reductions in average daily step count in those patients wearing a removable knee-high device compared with wearing a healing sandal (1404 vs 4022, $P < 0.01$).[43] We conclude that removable knee-high devices reduce plantar pressures at ulcer sites and weight-bearing activity more effectively than removable ankle-high devices and therefore have more potential for healing plantar neuropathic forefoot ulcers when worn.

Adverse events for removable knee-high offloading devices are likely to be the same as for nonremovable knee-high devices. However, ankle-high offloading devices may potentially have fewer adverse events compared with knee-high offloading devices as they either have lower or no device walls that reduce the risk for abrasions, lower-leg ulcers, imbalance, and gait challenges,[33] and they may have lower treatment discontinuation.[20] One high-quality meta-analysis including two low-quality RCTs[38,43] found higher treatment discontinuation with removable knee-high devices compared with removable ankle-high devices ($P < 0.01$).[34] One high-quality RCT found no differences in adverse events between a removable knee-high device and either a removable cast shoe or forefoot offloading shoe (45% vs 30% vs 25%, respectively, $P = 0.377$).[20] Further, those events reported were mostly minor pressure points, blisters, and abrasions, with smaller numbers of serious hospitalization and fall events (15% vs 5% vs 5%, respectively, P = not reported).[20] A low-quality RCT also found no difference in adverse events for new ulcers or infections between removable knee- and ankle-high devices (15% vs 13%, $P > 0.05$).[43] A third low-quality RCT reported no adverse events in either group.[38] We conclude there is no clear difference in adverse events between removable knee- and ankle-high offloading devices.

We identified one low-quality RCT reporting preference outcomes that found no difference in patient satisfaction, comfort, or preference to wear the device again between wearing a removable knee- and ankle-high offloading device ($P > 0.05$).[43] The same study reported that the removable knee-high group was more nonadherent than the removable ankle-high group (11% vs 0% of participants were deemed nonadherent with their device and were removed from the study as drop outs, P = not reported).[43] A high-quality RCT also reported non-significantly higher nonadherence with removable knee-high offloading than with two removable ankle-high devices (17% vs 5% vs 5% of the time, $P = 0.236$).[20] We conclude patients have similar preference for removable knee- and ankle-high devices, and nonadherence does not seem to be very different between devices, although one should note that these studies were not powered to detect a difference in nonadherence between devices.

One low-quality RCT reported on costs, finding that one-off device costs were higher for a removable knee-high offloading device (walker) than an ankle-high offloading device (half shoe) ($150-200 vs $25-75, P = not reported).[38] Based on only one, already rather old, study, we provisionally conclude that the device costs of treatment are higher in removable knee-high devices than in removable ankle-high offloading devices.

Contraindications for the use of removable knee-high offloading devices, based predominantly on expert opinion, include presence of both moderate infection and moderate ischaemia or severe infection or severe ischaemia. We refer to the IWGDF infection and PAD guidelines and the IWGDF glossary for definitions on infection and ischaemia.[27,28,46]

In summary, based on similar healing outcomes in a small number of mostly low-quality controlled studies, but consistently superior plantar pressure offloading and induced reduction of walking activity and thus superior healing potential in those studies and other non-controlled studies, we rate the quality of evidence favouring removable knee-high devices over removable ankle-high devices as low. Additionally, considering this potential healing benefit, no apparent differences in adverse events or preferences, and slightly higher nonadherence and treatment costs with removable knee-high offloading, we favour removable knee-high offloading over ankle-high offloading in our recommendation but grade the recommendation as weak. Nevertheless, as such a device is removable and there is potential for nonadherence, we stress that the patient should (repeatedly) be educated on the benefit of adherence to wearing the device to improve the effectiveness of the device for healing.[55]

Recommendation 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).

Rationale

Overall, evidence indicates that removable and nonremovable knee-high offloading devices give better clinical outcomes or potential for healing than ankle-high devices (see rationales for Recommendations

1 and 2). However, there may be contraindications (see rationales for Recommendations 1 and 2) or patient intolerance for wearing a knee-high device, such as expected or experienced device-induced gait instability, abrasions or other complications from the cast or device wall, or patient refusal to wear the device. Another reason may be lack of available knee-high offloading devices. In those cases, removable ankle-high offloading can be considered. This includes ankle-high walkers, cast shoes, half shoes, forefoot offloading shoes, postoperative healing shoes, and custom-made temporary shoes.

Our systematic review identified[31] no controlled studies specifically comparing removable ankle-high devices to conventional or standard therapeutic footwear or other offloading interventions, for effectiveness of healing, surrogate healing outcomes, adverse events, patient preferences, or costs.

Several noncontrolled studies show that 70% to 96% of plantar foot ulcers can be healed in a reasonable time frame (mean 34-79 d) with ankle-high removable offloading devices, provided they are used regularly.[68-72] Multiple cross-sectional studies also consistently found that a variety of removable ankle-high offloading devices were more effective in reducing plantar pressure at the forefoot than a variety of footwear interventions (custom-made, therapeutic, extra-depth, conventional, or standard footwear).[53,54,64,65,73-77] No studies were found for weight-bearing activity or adherence. Thus, we conclude that removable ankle-high devices have higher potential for healing than conventional or therapeutic footwear or other nonknee-high offloading interventions when worn.

Adverse events comparing ankle-high offloading devices to footwear interventions have not been reported in the literature. Based on expert opinion, we consider ankle-high offloading devices to have a low adverse event rate and comparable to conventional or therapeutic footwear. Adverse events may include minor abrasions, blisters, minor gait challenges or instability, and, with poor casting, new ulcers with cast shoes. However, it should be noted that the traditional form of half shoes, that only support the midfoot and heel,[71] contrary to a forefoot offloading shoe, are contraindicated owing to risk of midfoot fracture.

Two studies reported on patient preferences.[74,75] They showed that patient comfort was similar between ankle-high walkers and standard footwear[75] but was lower in different forefoot offloading shoe models compared with standard footwear.[74] A recent study reported that the use of ankle-high walkers had similar patient comfort levels to athletic shoes when the contralateral leg had a shoe raise to compensate for leg-length discrepancy.[53] Based on expert opinion, patients may prefer an ankle-high walker over a forefoot offloading shoe, because the latter has a significant negative rocker outsole that may cause problems during gait.

We found no studies on costs. The cost of treatment is likely to be low for some ankle-high offloading devices (eg, cast shoes and forefoot offloading shoes), particularly when they require no replacement during treatment. However, costs for therapeutic footwear are expected to be higher than for these other ankle-high devices.

In summary, all evidence for this recommendation comes from cross-sectional studies and expert opinion, and therefore the quality of evidence for this recommendation is rated as low. When weighing the potentially higher healing benefits of removable ankle-high devices over conventional or therapeutic footwear, better outcomes on plantar pressure, with expected similar low incidence of harms, patient preferences, and costs, we grade this recommendation as strong. In particular, for countries with low resources or lack of trained cast technicians, these removable ankle-high devices may be an appropriate offloading intervention for treating plantar neuropathic forefoot ulcers.

3.3 | Footwear

PICO 4: In people with a plantar DFU, are conventional or standard therapeutic footwear compared with other (non-surgical) offloading interventions effective to heal the DFU?

Recommendation 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 abovementioned offloading devices is available (Strong; Moderate).

Rationale

There are no studies that show the efficacy of conventional or standard therapeutic footwear as the primary intervention to heal neuropathic plantar foot ulcers. In the few studies in which this footwear has been tested as a comparison intervention, the conventional or standard therapeutic footwear proved inferior to other offloading devices (custom-made or prefabricated, nonremovable or removable, knee- or ankle-high devices) to both reduce mechanical stress and effectively heal a neuropathic plantar forefoot ulcer. Two high-quality meta-analyses found nonremovable knee-high offloading devices were 62% to 68% more likely to heal a neuropathic plantar forefoot ulcer than therapeutic footwear ($P < 0.01$).[34,37] Another high-quality meta-analysis,[35] including two lower-quality RCTs,[49,78] reported removable offloading devices were 76% more likely to heal these ulcers than therapeutic footwear, but the difference was non-significant ($P = 0.184$).[35] A low-quality RCT not included in the meta-analyses found no difference between TCCs, nonremovable knee-high walkers or modified footwear for healing rates ($P = 0.99$) and time-to-healing ($P = 0.77$).[61]

Four low-quality RCTs reported adverse events using therapeutic footwear, and all were compared with TCCs. Two found similar low proportions of abrasions or new ulcers for TCCs (0%-4%) and footwear (0%-4%, no P = not reported).[61,79] While another two found lower proportions of infections with TCC (0%-3%) compared with footwear (19%-26%) ($P < 0.05$).[49,78] One high-quality meta-analysis reported significantly more treatment discontinuations because of a combination of adverse events, voluntary withdrawal or losses to follow-up in those patients treated with TCCs compared with therapeutic footwear ($P = 0.003$).[34]

One low-quality RCT reported on patient preference and found that those patients using TCCs and those using therapeutic footwear had no difference in an acceptance of treatment score (*P*="not significant").[79] One low-quality RCT reported the material costs for modified footwear were lower than for TCCs and nonremovable walkers in treating patients with a foot ulcer ($7 vs $20 vs $35, respectively; $P < 0.01$).[61] However, the aforementioned large health technology assessment showed therapeutic footwear was far less cost-effective than other nonremovable (TCC and nonremovable knee-high offloading device) and removable offloading devices (removable walkers).[34]

Taken together, based on data from multiple meta-analyses consistently favouring the use of offloading devices over conventional or standard therapeutic footwear to heal neuropathic plantar forefoot ulcers, we rate the quality of evidence as moderate. Based additionally on worse outcomes for adverse events and costs using therapeutic footwear, and similar outcomes for preferences, we grade this recommendation as strong.

3.4 | Other offloading techniques

PICO 5: In people with a plantar DFU, are any other offloading techniques that are not device or footwear-related, effective to heal a DFU?

Recommendation 4b

If none of the abovementioned offloading devices is available, 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).

Rationale

Despite many practitioner surveys reporting high use of other offloading techniques (particularly for felted foam),[17,18] there has been limited evidence to support any other offloading techniques to effectively heal a neuropathic plantar foot ulcer.[10] Other offloading techniques are defined as any intervention undertaken with the intention of relieving mechanical stress from a specific region of the foot that is not an offloading device, footwear, or surgical approach.

Our updated systematic review[31] identified just three low-quality controlled trials[70,80,81] on other offloading techniques to heal a neuropathic plantar foot ulcer. All three trials investigated felted foam padding.[70,80,81] No controlled trials were identified for bed rest, crutches, wheelchairs, offloading dressings, callus debridement, foot-related strength and stretching exercises, or gait retraining to effectively heal DFUs.

One low-quality RCT showed significantly shorter time-to-healing with felted foam worn in a postoperative shoe when compared with a half shoe used without the felted foam.[81] Another low-quality RCT showed no difference in ulcer size reduction at 4 weeks between felt fitted to the foot worn in a postoperative shoe compared with felt fitted to a postoperative shoe.[80] A low-quality retrospective cohort study found no differences in ulcers healed or time-to-healing between felted foam fitted to the foot in a postoperative shoe, felted foam fitted to a postoperative shoe, a walking splint or TCC.[70] Additionally, two cross-sectional studies found that felted foam in addition to postoperative shoes moderately reduced plantar pressures over 1 week compared with postoperative shoes alone.[82,83] We conclude that felted foam used with an ankle-high offloading device may be more effective than wearing just the device alone, to reduce plantar pressure and heal a plantar neuropathic DFU. Furthermore, we consider the same effectiveness may be apparent if the felted foam was used with an appropriately fitting conventional or standard therapeutic footwear as opposed to just wearing the footwear alone.

The only two controlled studies reporting adverse events found similar levels of adverse events for the use of felted foam in combination with an ankle-high offloading device compared with an ankle-high device alone, including minor skin tear/maceration (10% vs 20%) and new infection (25% vs 23%).[80,81] No controlled studies were identified that investigated patient preferences or costs; however, patients will likely value and prefer the use of felted foam as an easy-to-use modality. The costs of felted foam are relatively low, but it does require frequent replacement, by a clinician, the patient, a relative, or a home-care nurse. Based on the evidence from the studies performed, felted foam may be used in ankle-high offloading devices or when no offloading devices are available then may be used in addition to appropriately fitting conventional or standard therapeutic footwear. We define appropriately fitting footwear as providing sufficient room for the patients' foot shape and the added felted foam. This enables for some offloading treatment of the ulcer if other forms of offloading devices, as mentioned in Recommendations 1 to 3, are not available. Whether the felted foam is fitted to the foot or to the shoe or insole does not make a difference in healing, although fitting it to the foot provides some offloading when the patient is nonadherent to wearing the shoes.

In summary, based on few low-quality controlled studies, and the difficulty in determining the added effect of felted foam in these studies, we rate the quality of evidence as low. Any benefit found with the use of felted foam will likely outweigh the harm. Together with a lack of information on costs and patient preference, we rated the strength of this recommendation as weak. Finally, based on the evidence from all offloading intervention studies performed and our expert opinion, felted foam may be used in addition to offloading devices, or if no offloading devices are available then felted foam may be used in combination with appropriately fitting conventional or standard therapeutic footwear as the fourth choice of offloading treatment for healing the ulcer. However, felted foam should not be used as a single treatment modality.

3.5 | Surgical offloading techniques

PICO 6: In people with a DFU, are surgical offloading techniques compared with non-surgical offloading interventions effective to heal the DFU?

Recommendation 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).

Rationale

Surgical offloading techniques have been traditionally used for plantar ulcers that are considered hard-to-heal with non-surgical offloading interventions.[58] These techniques change the structure of the foot and therefore provide a more permanent offloading solution for areas of elevated mechanical stress, even when the patient is not adherent to wearing an offloading device. However, surgical offloading potentially comes with increased risk of complications.[58] Surgical offloading is defined as a surgical procedure undertaken with the intention of relieving mechanical stress from a specific region of the foot and typically include Achilles tendon lengthening (ATL), metatarsal head (MTH) resection, osteotomy, arthroplasty, ostectomy, exostectomy, external fixation, flexor tendon transfer or tenotomy, and tissue fillers such as silicone or fat.

Our updated systematic review[31] identified one high-quality meta-analysis on this topic.[84] This meta-analysis included two RCTs, one of high quality[85] and one of low quality,[86] and investigated ATL and gastrocnemius recession in addition to TCC compared with TCC alone.[84] It found no differences in proportion of ulcers healed or time-to-healing.[84] The high-quality RCT did find small effects, but these were not statistically significant, on ulcers healed (100% vs 88%, $P = 0.12$) and time-to-healing (40.8 vs 57.5 days, $P = 0.14$) favouring ATL + TCC over TCC alone in patients with reduced ankle dorsiflexion.[85] Four retrospective noncontrolled studies showed 80% to 95% healing in 3 months with ATL.[87-90]

One high-quality RCT found that MTH resection(s) in combination with therapeutic footwear compared with therapeutic footwear alone healed more ulcers (95% vs 79%, $P < 0.05$) with shorter time-to-healing (47 vs 130 d, $P < 0.05$).[91] Three low-quality retrospective controlled cohort studies also showed shorter time-to-healing (by 21-350 d, $P < 0.05$) with MTH resection than non-surgical offloading intervention (removable walker, healing sandals, and therapeutic footwear).[92-94] Additionally, six noncontrolled studies showed positive effects of single or pan MTH resection in time-to-healing of plantar neuropathic metatarsal head ulcers, in patients in whom non-surgical treatment had failed.[95-100]

Two small lower-quality retrospective controlled cohort studies investigated metatarsal-phalangeal joint arthroplasty in addition to TCC and found shorter time-to-healing (by 24-43 d, $P < 0.05$) compared with nonremovable offloading devices (TCC or nonremovable walker).[101,102] Four noncontrolled studies showed between 91% and 100% healing of plantar, lateral, or dorsal toe ulcers using interphalangeal or metatarsal-phalangeal joint arthroplasty.[103-106]

The potential harm of applying these surgical techniques includes postoperative complications, infection, gait problems, acute Charcot neuro-osteoarthropathy, ruptured Achilles tendons, and transfer ulcers.[87,97,99] The controlled trials reporting adverse events found mixed results.[85,91-93,101,102] These included a significant increase in heel ulcers after Achilles tendon lengthening compared with TCC alone (13% vs 0%, $P < 0.05$) but similar number of abrasions (13% vs 18%), infection (3% vs 0%), amputation (0% vs 3%), falls (7% vs 0%), and death (10% vs 9%).[85] Most other trials compared surgical techniques to removable offloading devices or footwear and found mixed results on adverse events that were not significantly different between interventions, including infection (5%-40% vs 13%-65%) and amputation (5%-7% vs 10%-13%) ($P > 0.05$).[91-93,101] One recent low-quality controlled study of MTH resection(s) found significant decreases in number of hospitalizations and infections compared with non-surgical offloading controls described as "nonweight bearing and sometimes specialized footwear" ($P < 0.05$).[94]

Only one controlled study reported on patient preferences, finding higher discomfort in a surgical offloading group during healing ($P < 0.05$) but higher satisfaction after treatment when compared with therapeutic footwear ($P < 0.01$).[91] We found no controlled trials investigating costs. Costs of treatment for surgical interventions are generally considered higher than for non-surgical treatment, although one study showed no difference in costs between MTH resection and non-surgical treatment of a plantar foot ulcer.[99]

In summary, there is some evidence to support surgical vs non-surgical offloading to improve time-to-healing of plantar foot ulcers that prove to be hard-to-heal after unsuccessful non-surgical treatment. However, based on the low number of controlled trials for each surgical intervention, the general low quality of these trials and the mixed benefits, we consider the quality of evidence for this recommendation is low. When considering that the benefits predominantly relate only to time-to-healing and not to healing proportion, it is unclear if the benefits outweigh the potential harm. Patients may value and prefer surgical treatment after long and unsuccessful non-surgical treatment (such as with knee-high offloading devices). Thus, we rate the strength of this recommendation as weak. However, we recommend considering surgical offloading when non-surgical offloading treatment fails in healing the foot ulcer. Surgical offloading is contraindicated when severe ischaemia is present; the ischaemia should be primarily addressed in that case.

Recommendation 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).

Rationale

Two recent systematic reviews were identified on the efficacy of digital flexor tenotomy on DFU outcomes.[107,108] Both reviews identified the same five noncontrolled studies[109-113] and one of the reviews identified a sixth noncontrolled study.[114] The larger systematic review reported an overall healing rate of 97% in a mean 29.5 days.[107] The majority of the studies that reported on adverse events, reported moderate incidences of infection (2%-7%), transfer lesions (5%-16%), amputations (2%-9%), or ulcer recurrence (0%-21%).[107] None reported patient preference or cost outcomes.

While controlled studies on this topic are lacking, we consider this procedure to be a promising intervention in patients with hammertoes and recalcitrant digital ulcers in particular that fail non-surgical

treatment. However, the quality of the evidence for this recommendation is low. The possible benefits of digital flexor tenotomy may outweigh the potential harm. Patients who have digital ulcers that will not heal with non-surgical treatment may value and prefer treatment by flexor tenotomy, which may be performed in an outpatient setting, without need for subsequent immobilization. Costs and cost-effectiveness of this procedure have not been evaluated. Thus, we consider the strength of this recommendation to be weak.

3.6 | Other ulcers

PICO 7: In people with a plantar DFU complicated by infection or ischaemia, which offloading intervention is effective for healing the DFU?

Recommendation 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).

Recommendation 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).

Recommendation 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).

Rationale

Many plantar ulcers seen in clinical practice are not purely neuropathic ulcers but have some level of infection and/or ischaemia present. Because of the neuropathic origin and mechanical stress that often caused and still affects these ulcers, they do require offloading. However, health care professionals should be more cautious about which kind of offloading to use and when to use offloading if ulcers are complicated by infection or ischaemia.

As identified in Recommendation 1, nonremovable knee-high offloading devices can be considered for healing neuropathic plantar forefoot ulcers that have mild infection, mild-to-moderate amounts of exudate, or mild ischaemia.[34-36,39,45,52] Nonremovable offloading should not be used for moderate-to-severe infections or heavily exudating ulcers that require frequent local wound care or inspection, or moderate-to-severe ischaemia, where there may be doubt on the potential for wound healing or when both mild infection and mild ischaemia are present.[34-36,39,45,52]

Removable knee-high offloading devices can be considered for healing ulcers with both mild infection and mild ischaemia present or with heavy exudate, moderate infection, or moderate ischaemia present, which all require frequent local wound care or inspection. However, if a neuropathic plantar forefoot ulcer is complicated by both moderate infection and moderate ischaemia or by severe infection or severe ischaemia, then the infection or ischaemia should primarily be addressed and an offloading intervention should be applied based on the patient's function, ambulatory status, and activity level.

The overall quality of evidence for these recommendations is low as they are based on only a few observational studies,[39,45,47,48] interpretations from small subgroups of patients with these complications in some larger controlled trials,[49-51] and expert opinion, but with the notion that these plantar ulcers still require offloading for healing.[33,34] Furthermore, based on the lack of evidence, data missing on harm and benefits, patient preferences, and costs, the strength of these recommendations is weak.

PICO 8: In people with a plantar heel DFU, which offloading intervention is effective to heal the DFU?

Recommendation 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).

Rationale

Neuropathic plantar heel ulcers are less prevalent than forefoot ulcers[115] but are considered more of a challenge to offload and heal.[58] There is a paucity of evidence available on offloading interventions to treat plantar heel ulcers.[58]

Our updated systematic review[31] identified only one controlled study that specifically reported healing outcomes for plantar heel ulcers.[78] This low-quality RCT reported that those ulcers offloaded with a TCC had shorter time-to-healing than those using therapeutic footwear (69 vs 107 d), but no statistical significance was reported.[78] Another high-quality RCT compared a custom-made fibreglass heel cast with standard wound care in patients with heel ulcers, but of which most (72%) were nonplantar.[21] The authors did not specifically report on plantar heel ulcers. This RCT is discussed under nonplantar ulcers.

As outcomes on healing were limited, we assessed surrogate measures for offloading as previously recommended[11] and identified three controlled trials investigating plantar pressure reductions. One high-quality RCT found slightly greater heel plantar pressure reductions from baseline barefoot pressure in participants wearing a TCC compared with those wearing a knee-high walker, but this difference was not significant (54% vs 40%, $P = 0.11$).[62] Another high-quality RCT found a significant increase in heel plantar pressures in those

undergoing an ATL procedure in combination with a TCC compared with those treated with a TCC alone (70.6 ± 28.1 vs 55.8 ± 30.7 N/cm^2, P = 0.018).[116] The other low-quality nonrandomized controlled trial reported heel plantar pressures in a removable ankle-high walker intervention increased by 10% from baseline pressures in conventional footwear.[117]

A number of cross-sectional designed studies also investigated the effect of different offloading interventions on heel plantar pressures.[65,66,118] Three investigated TCCs compared with knee-high walkers and found mixed results. One found TCCs had slightly greater heel plantar pressure reduction,[118] another found knee-high walkers reduced more heel pressure,[65] and a third found they were the same in pressure relief.[66] Several others found removable knee-high devices (walkers and bivalved TCCs) had slightly greater heel plantar pressure reductions than ankle-high devices (walkers, cast shoes, and postoperative healing shoes)[65-67,76] but not always to a statistically significant level.[66,67] Other studies found that removable ankle-high devices give greater heel plantar pressure reduction than footwear (therapeutic and standard).[74-76] Heel-relief shoes are specifically designed to offload the heel but have not been tested for efficacy on pressure relief to date.

No controlled studies specifically reported on adverse events with treating plantar heel ulcers. However, one RCT found an increase in new plantar heel ulcer development in those undergoing ATL in combination with a TCC to heal forefoot ulcers compared with a TCC alone but did not report significance (13% vs 0%).[85] Otherwise, we suggest the adverse events from different offloading interventions would be similar to those to heal a forefoot DFU. Thus, we consider that nonremovable and removable knee-high devices have similar low incidence of harm but potentially slightly higher incidence of harm than removable ankle-high devices. No studies have reported on preferences or costs for treating plantar heel ulcers.

In summary, there is some evidence that using knee-high offloading devices may be more effective in time-to-healing and reducing plantar pressures on the heel than other offloading interventions. However, based on one low-quality controlled trial comparing subgroups and several noncontrolled studies, we rate the quality of evidence as low. When considering the benefits predominately related to small effects on time-to-healing and plantar pressure reductions compared with other offloading interventions, and given the paucity of data on harms, patient preferences, and costs, we rate the strength of this recommendation as weak. Therefore, we recommend considering using a knee-high offloading device or any other offloading intervention that can demonstrate effective reduction of plantar pressure on the heel.

PICO 9: In people with a nonplantar DFU, which offloading intervention is effective to heal the DFU?

Recommendation 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).

Rationale

Overall, there is very little evidence available on how to treat nonplantar foot ulcers, despite these ulcers being prevalent and also needing relief from mechanical stress.[115] Our updated systematic review[31] identified just one controlled trial that could partly address this topic.[21] This large high-quality RCT compared a custom-made, fibreglass heel cast in addition to usual care with usual care alone ("usual care was not uniform") in patients that mostly (72%) had nonplantar heel DFUs.[21] The study found no differences in ulcer healing, adverse events, or patient preferences but did find the heel cast had higher overall costs.[21] Although patients with nonplantar DFU made up the majority of included patients, the RCT did not report outcomes specifically for the nonplantar DFU.[21]

Therefore, until new evidence becomes available and depending on the location of the nonplantar ulcer, we recommend that various modalities can be considered, including ankle-high offloading devices, modifications to conventional or therapeutic footwear, toe spacers, and orthoses. Footwear does not have to be therapeutic but can consist of properly fitting conventional footwear that prevents, or is modified to prevent, direct contact with the ulcer. The modality chosen should be based on the principal that it prevents any mechanical stress or contact with the ulcer and is an appropriate fit for the rest of the foot so as not to produce new lesions.

Based on the RCT and our expert opinion, we expect any potential harm such as lesions directly caused by these other modalities on the foot to be minimal. We also anticipate that patients will likely prefer the use of these modalities for treatment of a nonplantar foot ulcer, as they should increase the protection of their ulcer, compared with standard care. We also suggest the additional costs for applying these modalities are relatively low.

In summary, because of the paucity of data, we rate the quality of evidence for this recommendation as low. However, we assessed the strength of this recommendation as strong. This is based on our opinion that these modalities compared with standard wound care alone would produce benefits in terms of DFU healing, mechanical stress reduction, and patient preference that should outweigh any harms or small costs of treatment.

4 | KEY CONTROVERSIES AND CONSIDERATIONS

1. Since the previous guidelines in 2015, the TCC is no longer considered the only gold standard treatment option to effectively heal plantar forefoot ulcers. Prefabricated removable knee-high walkers that are rendered nonremovable have been shown with more evidence over the last 4 years, to be as effective as the TCC. This has changed the traditional view on offloading, in which the main comparison was TCC vs any other offloading interventions, but is now nonremovable knee-high offloading

devices vs other offloading interventions. This has positive implications for those settings where casting materials or trained casting technicians are not available. In these settings, depending on patient preferences and fit, reliance on the correct use of prefabricated removable walkers made nonremovable for offloading is appropriate.

2. In the large number of studies conducted on the efficacy of the TCC or nonremovable knee-high walkers, many different versions, types, and methods of devices and casts have been used. These different versions of devices may potentially lead to different outcomes and varied costs. Trials are needed in which these different versions of casting or walkers used are compared with each other, so that a more informed decision can be made on which type of cast or walker is best to use for nonremovable knee-high offloading.
3. Likewise, there are many different offloading devices that are defined as an "ankle-high offloading device" such as ankle-high walker, forefoot offloading shoe, cast shoe, healing sandal, postoperative healing shoe, and custom-made temporary shoe. These devices can be just above ankle or below ankle, prefabricated or custom-made and may lead to different outcomes and varied costs. More consideration should be given to studying the efficacy of each of these ankle-high offloading devices in healing foot ulcers to determine which of these devices is most effective in healing and plantar pressure outcomes, so that more informed decisions can also be made in clinical practice on which type is best to use for removable ankle-high offloading.
4. Many RCTs on offloading do not directly measure the degree to which the mechanical stress on the ulcer has been changed by the offloading intervention. Such measurements improve our understanding of the role of offloading in healing, as do several other outcomes. A stronger focus is required on measuring the factors impacting on the mechanical stress levels that lead to different healing outcomes, such as plantar pressure, shear stress, weight-bearing activity that includes steps and standing duration, and adherence to using offloading devices.
5. Offloading studies have focused almost exclusively on the treatment of noncomplicated neuropathic plantar forefoot ulcers. Little data are available on the value of offloading in healing plantar foot ulcers complicated by infection or ischaemia, heel ulcers, or nonplantar ulcers, even though these ulcers are now more common than years ago. We have now addressed offloading these specific foot ulcers in separate PICOs and recommendations, which are largely based on expert opinion. Properly designed studies on offloading ulcers other than the noncomplicated neuropathic plantar forefoot ulcer are urgently needed.
6. Adherence to an intervention is crucial in healing foot ulcers. It is consistently reported that those who do not adhere to an intervention present with worse healing outcomes. A stronger focus is required, both in research and in clinical practice, on the measurement and improvement of offloading treatment adherence.
7. Surgical offloading has primarily been applied to heal foot ulcers in selected patients, typically where other non-surgical offloading interventions have failed. The evidence is based on only a few older controlled studies and more high-quality RCTs on surgical offloading procedures are required to determine the impact of surgical interventions on the healing of both noncomplicated and complicated foot ulcers.
8. Information on harms and other adverse events are critical in clinical decision-making on offloading treatment. Most RCTs are underpowered for adverse events as outcome. It is unlikely that an RCT will focus on adverse events as the primary outcome. However, if trials report adverse events using the same definitions, there is the possibility of pooling data in a meta-analysis that may better address the topic of adverse events. We recommend future trials to ensure that they collect adverse events based on standard definitions as recommended by Jeffcoate et al.[11]
9. Costs and cost-effectiveness have also received little attention in offloading studies, despite the fact that reimbursement through insured care is more and more dependent on proven cost-effectiveness. While some cost studies have been performed since our previous guidelines in 2015, more attention is still warranted in view of the continuing pressure on health care cost containment.
10. The majority of interventions discussed are 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 healing in lower income regions where climate and/or resources may be a factor in choice of offloading device, adherence to wearing the device, and its efficacy.

5 | CONCLUDING REMARKS

The global patient and economic burden of diabetic foot disease can be considerably reduced when evidence-based treatment is implemented by health care professionals and multidisciplinary teams working on this medical problem. Offloading is arguably one of the, if not the, most important intervention with the strongest evidence available for healing foot ulcers and reducing the global burden of diabetic foot disease. We think that following the recommendations for offloading treatment of diabetic foot ulcers in this guideline will help health care professionals and teams provide better care for persons with diabetes who have a foot ulcer and are at risk for infection, hospitalization, and amputation.

We encourage our colleagues, especially those working in diabetic foot clinics, to consider developing some forms of surveillance (eg, registries and pathways) to monitor and attempt to improve their outcomes in persons with diabetes and a foot ulcer. We also encourage our research colleagues to consider our key controversies and considerations and to conduct well-designed studies[11] in areas of offloading in which we find gaps in the evidence base so to better inform the diabetic foot community in the future on effective offloading treatment for persons with diabetes and a foot ulcer.

GLOSSARY

Adverse events in relation to offloading treatment: general or local complications related directly or indirectly to the intervention regardless of whether they are serious. These include but are not limited to falls, new preulcerative lesion formation (abrasions, calls, and blisters), new DFU formation, acute Charcot foot, infection, hospital admissions, amputation, and death.

Adherence to offloading intervention: The extent to which a person's behaviour corresponds with agreed recommendations for treatment from a health care provider, expressed as quantitatively as possible; usually defined as the proportion of time using the prescribed offloading intervention of the total time in which the intervention is prescribed to be used (eg, % of the total weight bearing time that the patient was wearing the prescribed offloading device).

Ambulatory activity: defined as the weight-bearing dynamic activity, often expressed as average daily steps or strides.

Ankle-high offloading device: an offloading device that extends no higher up the leg than just above the ankle. Includes ankle-high walker, forefoot offloading shoe, cast shoe, healing sandal, postoperative healing shoe, and custom-made temporary shoe.

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.

Complicated DFU: a plantar DFU that is complicated by infection and/or ischaemia.

Conventional footwear: off-the-shelf footwear with no specific properties for fitting or intended therapeutic effect.

Custom-made insole: An insole that is custom-made to the individual's foot using a 2D or 3D impression of the foot and that is often built-up in a multilayer construction. This may also incorporate other features, such as a metatarsal pad or metatarsal bar. The insole is designed to conform to the shape of the foot, providing cushioning and redistribution of plantar pressure. The term "insole" is also known as "insert" or "liner."

Custom-made (medical grade) footwear: Footwear uniquely manufactured for one person, when this person cannot be safely accommodated in prefabricated (medical grade) footwear. It is made to accommodate deformity and relieve pressure over at-risk sites on the plantar and dorsal surfaces of the foot. In-depth assessment, multiple measurements, impressions or a mould, and a positive model of a person's foot and ankle are generally required for manufacture. This footwear includes a custom-made insole. Also known as "bespoke footwear" or "orthopaedic footwear."

Custom-made temporary shoe: a unique, usually handmade 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.

Diabetes-related foot ulcer (DFU): see IWGDF definitions and criteria document.[46]

DFU healing: defined as number or percentage of healed DFUs by a fixed time (eg, % of DFUs healed in 12 wk of intervention) or time-to-healing a DFU.

Extra-depth footwear: Prefabricated footwear 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 with off-the-shelf footwear. Even greater depth is sometimes provided in footwear that is referred to as double depth or super extra-depth.

Footwear: defined broadly as any shoe gear and including insoles.

Forefoot offloading shoe: prefabricated shoe especially designed for relieving forefoot locations. The footwear has a specific shape with a wedge design raising the forefoot above the rearfoot, a rocker outsole, and minimal support of the forefoot. These shoes are usually worn unilaterally.

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.

Healed DFU: see IWGDF definitions and criteria document.[46]

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.

In-shoe (semi-)rigid orthoses: device put inside the shoe to achieve pressure reduction or alteration in the function of the foot. Can be prefabricated or custom-made

Knee-high offloading device: an offloading device that extends up the leg to a level just below the knee (eg, knee-high total contact cast (TCC), knee-high removable walker).

Nonplantar: see IWGDF definitions and criteria document.[46]

Nonremovable offloading device: an offloading device that cannot be removed by the patient (eg, TCC, removable knee-high walker rendered nonremovable [nonremovable walker], etc.).

Non-surgical offloading intervention: any intervention undertaken with the intention of relieving mechanical stress (pressure) from a specific region of the foot that does not involve a surgical procedure (includes offloading devices, footwear, and other offloading techniques).

Nonremovable walker: prefabricated removable, mostly knee-high, walker rendered nonremovable to the patient, by circumferentially wrapping with a layer(s) of fibreglass cast material or other closure technique (also known as "instant total contact cast").

Offloading: the relief of mechanical stress (pressure) from a specific region of the foot.

Offloading device: any custom-made or prefabricated device designed with the intention of relieving mechanical stress (pressure) from a specific region of the foot (eg, total contact cast (TCC), (non-) removable walker, knee-high walker, ankle-high walker, ankle foot orthoses, healing sandal, cast shoe, forefoot offloading shoe, etc.). Note that this excludes footwear.

Offloading intervention: any intervention undertaken with the intention of relieving mechanical stress (pressure) from a specific region of the foot (includes surgical offloading techniques, offloading devices, footwear, and other offloading techniques).

Other offloading techniques: any other technique undertaken with the intention of relieving mechanical stress (pressure) from a specific region of the foot that is not a surgical offloading technique, offloading device or footwear (eg, bed rest, crutches, wheelchairs, offloading dressings, felted foam/padding, callus debridement, gait retraining, foot-related exercises, patient education, etc.).

PICO: the PICO process is a technique used to frame evidence-based clinical questions. PICO stands for (P): Population; (I): Intervention; (C): Control; (O): Outcome.

Plantar: see IWGDF definitions and criteria document.[46]

Plantar pressure: see IWGDF definitions and criteria document.[46]

Postoperative healing shoe: prefabricated shoe with roomy and soft upper worn after an operation of the foot.

Removable offloading device: an offloading device that can be removed by the patient (eg, removable walker, forefoot offloading shoe, cast shoe, healing sandal, etc.).

Rocker outsole: rigid outsole with a sharp transition that aims to rock the shoe forward. during late support to allow walking without extension of the metatarsal-phalangeal joints.

Shoe modification: modification to an existing shoe with an intended therapeutic effect, for example, pressure relief.

Standard therapeutic footwear: off-the-shelf shoe with intended therapeutic effect but without any customization to the patient's foot.

Surgical offloading intervention: a surgical procedure or technique undertaken with the intention of relieving mechanical stress (pressure) from a specific region of the foot (eg, Achilles tendon lengthening, metatarsal head resection, osteotomy, arthroplasty, ostectomy, exostectomy, external fixation, flexor tendon transfer or tenotomy, silicone injections, tissue augmentation, etc.).

Therapeutic footwear: Generic term for footwear designed to have a therapeutic effect that cannot be provided by or in a conventional shoe. Custom-made shoes or sandals, custom-made insoles, extra-depth shoes, and custom-made or prefabricated medical grade footwear are examples of therapeutic footwear.

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

Total contact cast (TCC): a custom-made, well-moulded, minimally padded, knee-high nonremovable fibreglass or plaster cast that maintains total contact with the entire plantar surface and lower leg. The cast is often worn with an attachable sole that protects the cast and facilitates walking.

Ulcer area reduction: defined as the proportion of ulcer area reduction from baseline over a given period of time (eg, % ulcer area reduction at 4 or 6 wk from the start of the observation period).[1]

Uncomplicated DFU: noninfected, nonischaemic neuropathic DFU.

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CONFLICT OF INTEREST

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