Offloading diabetic foot ulcers: updates by the International Working Group on the Diabetic Foot

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Article points

1. Previous systematic review found little evidence to support the use of offloading techniques for the diabetic foot wound.
2. Updated systematic review provides sufficient evidence to support the healing of neuropathic plantar forefoot ulcers using surgical offloading and non-removable knee-high devices, such as a total contact cast or a non-removable walker.
3. There is a need for further studies to research which measures of offloading are most efficient in treatment where adherence to treatment recommendations and patient compliance is a factor.

Key words

- Case studies
- Guidelines
- Offloading techniques
- Prescriptive footwear
- Total contact casting

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Prescriptive footwear and offloading techniques to decrease pressure and protect lower-extremity ulcers have been used in the clinical practice of healing or preventing foot ulcers in patients with diabetes. A systematic review by the International Working Group on the Diabetic Foot (IWGDF) in 2008 found little evidence to support the use of offloading techniques for the diabetic foot wound. The IWGDF has published an update that includes guidelines and recommendations to better inform and improve the clinical practice of offloading as it pertains to ulcer treatment and prevention. This article highlights the new IWGDF guidelines and includes a discussion of new literature and key concepts (Bus et al, 2015). Case examples are also provided.

Prescriptive footwear and various offloading techniques to decrease pressure and protect lower-extremity ulcers have been used in the clinical practice of healing or preventing foot ulcers in patients with diabetes (*Table 1*). In 2008, a systematic review was conducted by the International Working Group on the Diabetic Foot (IWGDF). The review concluded that the evidence to support offloading techniques for the diabetic foot wound was quite limited and of relatively low quality (Bus et al, 2008). The IWGDF has published an update that includes guidelines and recommendations to better inform and improve the clinical practice of offloading as it pertains to ulcer treatment and prevention (Bus et al, 2015a).

Literature review

A discussion of recent literature around offloading and key concepts in ulcer management is reviewed as part of the new IWGDF guidelines.

Ulcer healing

To heal plantar forefoot ulcers, the evidence supports the claim that the use of non-removable, knee-high offloading modalities is better than removable forms of offloading. Evidence from two publications, including a systematic review and a meta-analyses published in 2013, revealed that in patients with diabetes, non-removable knee-high offloading devices (total contact cast or non-removable cast walkers) healed a higher proportion of non-ischaemic and non-infected neuropathic plantar forefoot ulcers at a faster rate, when compared with removable offloading modalities. There was a lower incidence of complications or side effects in patients treated with non-removable offloading devices (Moher et al, 2009). Total contact casting (TCC) has also been shown to heal 82% of ulcers compared with only 42% in patients who used a removable cast walker. The lower healing rate in patients who used a removable cast walker may be explained by poorer patient compliance and adherence to treatment guidelines (Gutekunst et al, 2011).

Ulcer prevention

There is evidence of sufficient quality to support therapeutic footwear for pressure relief that is worn by the patient to prevent plantar foot ulcer recurrence. Randomised controlled trials (RCTs) show the efficacy of therapeutic footwear for the relief of plantar pressures, which aids in the prevention of plantar foot ulcer recurrence. A study of 167 patients undertaken in 2009 showed significantly fewer ulcers and hyperkeratotic lesions at three months after the use of custom-made silicone orthoses when combined with standard of care (sharp debridement and use of

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Table 1. Types of offloading techniques.

Technique	Recommendation
Casting and prefabricated healing devices	Offloading with a non-removable knee-high device is superior to a removable knee-high device, forefoot shoe, cast shoe or custom-made temporary shoe to heal plantar neuropathic ulcerations. However, if a non-removable device is not tolerated by a patient or is contraindicated, then a removable knee-high cast walker, forefoot shoe, cast shoe or custom-made temporary shoe is acceptable for offloading a neuropathic ulceration.
Therapeutic footwear	At-risk patients with diabetes should be instructed not to walk barefoot, in thin-soled slippers or in socks in order to prevent occurrence of a foot ulceration. They should have properly fitted footwear or be prescribed therapeutic shoes with custom-made insoles, which have been shown to decrease plantar pressures.
Surgical offloading interventions	Where conservative measures have failed, multiple surgical interventions may be considered to prevent or heal a diabetic neuropathic ulceration in a high-risk patient, e.g. Achilles tendon lengthening, joint arthroplasty, single- or pan-metatarsal head resection, metatarsal osteotomy, digital flexor tenotomy.
Other offloading interventions	Felted foam, when used in combination with therapeutic footwear, may be used when other forms of offloading are not available.

a 'soft' accommodative insole and extra depth shoes), as compared with standard care alone. The incidence of recurrence was 1.1% and 15.4% in the treatment group and control group, respectively. Similarly, the incidence of recurrence of hyperkeratotic lesions was 41% in the treatment group and 84% in the control group (Scire et al, 2009).

Plantar pressure reduction

Plantar pressure can be reduced via the use of several modalities, including casts, walkers, therapeutic footwear and surgery. However, very few studies directly relate offloading to clinical outcome. An RCT conducted in 2011 compared in-cast pressure measurements in 23 patients who had active neuropathic plantar foot ulcers. These patients were offloaded with either TCC or a removable walker. TCC patients yielded significantly greater peak-pressure reduction at the midfoot (77% vs 63% for the removable walker) when using the TCC, compared with barefoot walking. Forefoot pressure was also reduced in the subject group that used the TCC compared with the removable walker (92% vs 84%) (Gutekunst et al, 2011).

Surgical offloading

Due to the limited number of controlled studies that have been conducted, clear evidence on the efficacy of surgical offloading to prevent or heal diabetic foot ulcers (DFUs) is limited. However, there are studies that demonstrate surgical offloading procedures to be effective as a curative means of treating these ulcers. These procedures have also been shown to have a preventive benefit when using certain procedures for primary healing (Bus et al, 2015b).

Surgical procedures that are performed most commonly include Achilles tendon lengthening (ATL), single- or pan-metatarsal head resections, joint arthroplasties, and/ or osteotomies. One RCT conducted in 2004 compared ATL in conjunction with TCC to patients with TCC alone. At seven

months' follow-up, the authors found that there were fewer recurrent ulcers in the ATL+TCC group compared with the TCC-alone group (15% vs 59%). A lower incidence of ulcer recurrence persisted after 2 years in the ATL+TCC group (38% versus 81%) (Mueller et al, 2003).

A similar study with a mean follow-up of three years revealed a lower incidence of ulcer recurrence in 138 patients who underwent ATL (2%) when compared with a group of 149 patients who underwent wound closure alone (25%). They also found a lower incidence of transfer lesions in the ATL group when compared with the wound closure–alone group (4% vs 12%). Of the six patients in the ATL group who had a transfer lesion, two patients had calcaneal transfer lesions and the remaining four had forefoot lesions. In comparison, transfer lesions were located within the forefoot in the primary wound closure group (Colen et al, 2013).

Digital flexor tenotomy is a common prophylactic procedure used to combat distal-oriented digital ulcerations. Several retrospective case series revealed ulcer recurrence rates between 0% to 20% over an 11–36-month follow-up, in a cumulative total of 231 patients treated with a percutaneous digital flexor tenotomy (Kearney et al, 2010; Laborde, 2007; Rasmussen et al, 2013; Schepers et al, 2010; Tamir et al, 2008; Tamir et al, 2014; van Netten et al, 2013).

Additionally, in 2003 a case-control study was conducted that included 41 patients with plantar hallux interphalangeal joint (IPJ) ulceration, which compared patients who had undergone a first metatarsalphalangeal joint (MPTJ) arthroplasty with patients who received local wound care and offloading for chronic hallux ulceration. Patients in the first MPTJ arthroplasty group healed significantly faster than control group (24.2 vs 67.1 days). The arthroplasty group also had a lower rate of recurrence vs the control group (4.8% vs 35%) (Armstrong et al, 2003).

Although not discussed in the IWGDF update, hallux IPJ arthroplasty is another well-documented procedure that is used as a curative or preventive offloading intervention for chronic plantar hallux ulcerations (Rosenblum et al, 1994; Lew et al, 2015). In 2014, a study compared patients who had undergone a hallux IPJ arthroplasty with patients who received local wound care and offloading for chronic hallux ulceration. The group who underwent surgical intervention had faster time to healing (3.5 weeks vs nine weeks), lower incidence of ulcer recurrence (8% vs 54%) and fewer amputations than that of the group who received only local wound care (0% vs 38%) (Lew et al, 2015).

Other offloading interventions

Studies on the efficiency of bed rest and the use of crutches, canes or wheelchairs to heal foot ulcers were not identified. Due to the limited number of studies, no clear evidence on the efficiency of other offloading interventions to prevent and/or heal DFUs could be concluded.

Case studies

The following case studies examine outcomes using TCC and surgical offloading techniques.

Case 1: total contact casting

A 58-year-old female with past medical history of uncontrolled diabetes, peripheral neuropathy, and morbid obesity presented with a chronic right heel ulceration for approximately one year. The

"Patients offloaded with total contact casting yielded significantly greater peak-pressure reduction at the midfoot compared with those who use a removable walker or who walk barefoot."

Figure 1. A chronic plantar right heel ulceration in a 58-year-old female with type 2 diabetes and peripheral neuropathy.
Figure 2. The plantar heel ulceration demonstrates successful wound healing with four weeks of offloading in a total contact cast.
Figure 3. After a total of six weeks of offloading in a total contact cast, the ulceration was completely healed and ready for gradual transition to walking in prescriptive shoes.

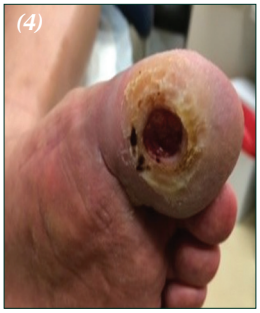


Figure 4. A neuropathic chronic plantar left hallux ulceration in a 63-year-old male with type 2 diabetes.
Figure 5. A concomitantly acutely infected plantar right hallux ulceration in the same 63-year-old male.

wound had developed after walking barefoot on hot asphalt and had not healed with conventional local wound care. She also had a wound to her left heel that healed uneventfully. Other important elements of the patient's past medical history included hypertension and atrial fibrillation.

On physical exam, the patient's vascular status was intact, but there was near-complete loss of protective sensation. The full-thickness ulceration on the right plantar foot measured 5 cm x 3 cm x 0.3 cm and was healthy in appearance, with some periwound hyperkeratosis, but no signs of infection (*Figure 1*).

The patient underwent offloading with the use of TCC. Wound debridement was performed weekly in conjunction with cast changes, and the wound improved by approximately 75% over the course of four weeks (*Figure 2*). After six weeks of offloading, the wound was completely epithelialised and healed (*Figure 3*). Reulceration and prevention was accomplished with custom pressure-relieving insoles and prescriptive depth-inlay shoe gear.

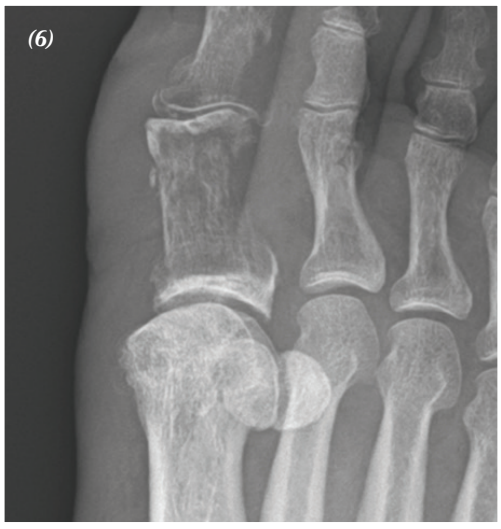
Case 2: surgical offloading of bilateral hallux ulcerations

A 63-year-old male with past medical history of uncontrolled diabetes and peripheral neuropathy presented with chronic and recurrent hallux ulcerations to both feet of more than three years. The patient's past medical history included hypertension, coronary artery disease, myocardial infarction and hyperlipidaemia. The patient's H_bA_{1c} was 6.8 mg/dl and his BMI was 37.5 kg/m^2.

On physical exam, the patient's neurovascular status was intact. The full-thickness ulcerations were bilateral to the plantar hallux interphalangeal joints. The left measured 2 cm x 1.5 cm x 0.3 cm deep (*Figure 4*) and was healthy in appearance. The right hallux ulcer measured 1.5 cm x 1.75 cm x 1.5 cm deep (*Figure 5*) and probed to bone through a sinus tract. There was purulent drainage with erythema, oedema and calor (warmth). Radiographs of the right hallux revealed cortical disruption and lytic changes at the first proximal phalangeal head (*Figure 6*). Magnetic resonance imaging also revealed osteomyelitis (*Figure 7*).

The patient underwent operative debridement, and resection of the affected hallux interphalangeal joint with implantation of antibiotic impregnated polymethyl methacrylate. Intraoperative bone cultures were positive for group *B Streptococcus* and *Staphylococcus aureus*. Bone pathology also revealed findings consistent with acute osteomyelitis.

The patient was followed on a weekly basis with local wound care and offloading. The antibiotic beads were removed at one week postoperative. His



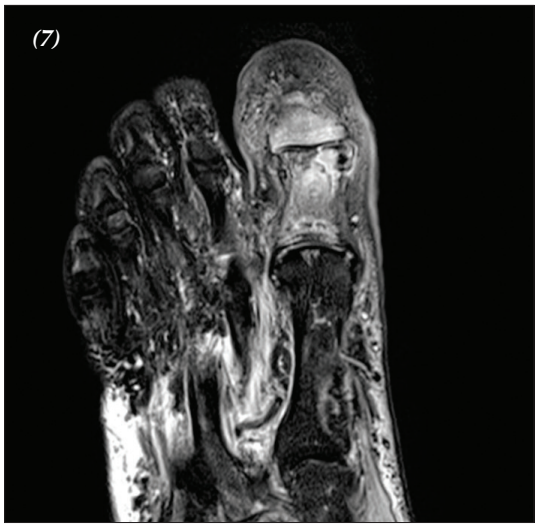


Figure 6. Plain radiography of the right foot revealed pathologic fracturing of the first proximal and distal phalanx secondary to osteomyelitis and hallux interphalangeal joint sepsis.
Figure 7. A T2 MRI of the right foot revealed increased signal intensity involving the first proximal and distal phalanges consistent with osteomyelitis.

postoperative course was complicated with dorsal wound dehiscence. The wound closed by secondary intention with debridement and local wound care. At six weeks postoperative, the plantar wound was healed completely (*Figure 8*).

The patient returned to the operating room to address the left hallux ulceration through a curative Keller arthroplasty and tendo-Achilles lengthening (*Figure 9*). This ulcer was healed by 10 days postoperative (Figure 10). Ulcer prevention was accomplished with custom pressure-relieving insoles, prescriptive depth-inlay shoe gear and out-sole rocker-bottom modifications. The patient had no ulcer recurrence through 12 months of follow-up.

Conclusions

This update to the 2008 systematic review provides sufficient evidence to support the healing of neuropathic plantar forefoot ulcers using non-removable knee-high devices, such as a TCC or a non-removable walker. Evidence also supports the use of therapeutic footwear for the reduction in plantar pressures, and to prevent plantar foot ulcer recurrence, assuming the footwear is worn by the patient regularly. The evidence base to support the use of therapeutic footwear for primary prevention of foot ulcer formation is still non-existent. No clear conclusions can yet be drawn regarding the efficacy and safety of surgical interventions or felted foam to heal foot ulcers or to prevent recurrence. However, there are a variety of successful procedures that are utilised as curative and prophylactic means of addressing diabetic foot ulcers. The strongest evidence to date supports Achilles tendon lengthening, flexor tenotomies, and digital arthroplasties.

There is a need for further studies researching which measures of offloading are most efficient in treatment where adherence to treatment recommendations and patient compliance are factors. Presently, there are a limited number of RCTs and controlled studies without select-bias in the literature. Regarding diabetic foot surgery and surgical offloading, further studies of higher quality would help define the proper level of evidence regarding offloading techniques. This, in turn, would also better inform clinicians about effective offloading treatments, so that they may be more widely accepted and implemented in diabetic foot practice throughout the world.

In conclusion, to heal neuropathic DFUs, knee-high irremovable walkers have the best level of evidence. In addition, to prevent diabetic foot wounds, the use of therapeutic footwear is recommended. Surgical correction may also be used. While data are admittedly promising, no definitive statements can be made and they must be used with caution after all conservative measures have been attempted and exhausted. Future high-quality studies will help us to determine the effectiveness of such treatments in offloading the DFU. ■

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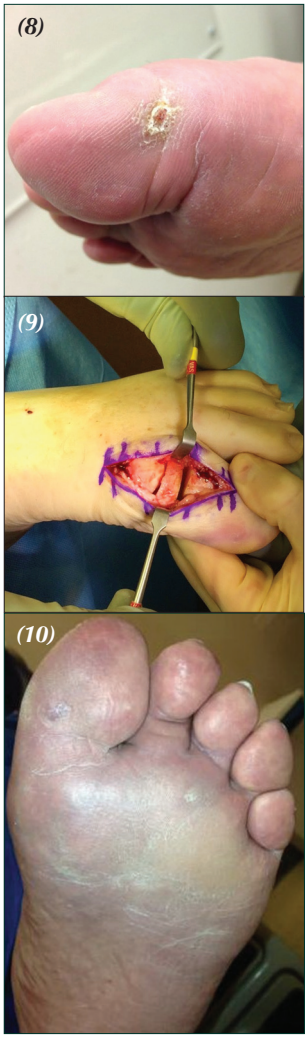

Figure 8. At six weeks after post-hallux interphalangeal joint arthroplasty and a short course of antibiotic therapy, the primary ulceration and dorsal incision healed with local supportive wound care.

Figure 9. A Keller (first proximal phalangeal base) resectional arthroplasty was performed to the left hallux to increase range of motion. This provided internal offloading of the plantar ulceration.

Figure 10. At 10 days postoperative, the plantar ulceration was completely healed.