



Review Article

Role of Offloading in the Management of Diabetic Foot Ulcers: Current Evidence and Emerging Approaches

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ABSTRACT

Introduction: Diabetic foot ulcers (DFUs) are one of the most common causes of hospitalizations and non-traumatic lower-limb amputation (NLLA) in the world and offloading mechanical stress is considered as the most effective intervention for healing plantar neuropathic ulcers.

Methods: A narrative synthesis of evidence from peer-reviewed randomized controlled trials, systematic reviews and meta-analyses and international guideline documents (International Working Group on the Diabetic Foot [IWGDF], Diabetes Care, Diabetic Medicine, and related journals) was carried out.

Results: Non-removable knee-high devices (particularly the total contact cast [TCC] and cast walkers that cannot be removed) have been shown to consistently improve time to healing and healing rate over removable devices, due to increased adherence to treatment. Removable cast walkers (RCWs) and therapeutic footwear are more functional but poorly adhered to by patients resulting in a diminished biomechanical advantage. Recurrent or refractory ulceration occurs and surgical offloading (Achilles tendon lengthening, metatarsal head resection, digital flexor tenotomy) contributes. New technologies such as smart insoles, orthoses printed with sensors, and walkers with sensors have potential to enhance adherence and tailor pressure redistribution.

Conclusion: Non-removable knee-high offloading is the evidence-based gold standard for plantar neuropathic DFUs, though practice is changing as technologies to improve adherence and surgical alternatives become increasingly available, especially when casting isn't a consideration or is poorly tolerated.

Keywords: Diabetic foot ulcer, Offloading, Total contact cast, Removable cast walker, Plantar pressure, Adherence, Surgical offloading, Smart insole.

INTRODUCTION

In the world today, diabetic foot ulcers are a significant issue, as it is estimated that 6.3% of all adults with diabetes have an ulcer on their foot and that they will have an ulcer at some point in their lifetime ranging from 19% to 34% [1]. People with diabetes experience an estimated 18.6 million new foot ulcers each year and up to 80% of lower extremity amputations in people with diabetes are preceded by a foot ulcer [2]. The prevalence rates vary significantly across the regions from 3.0% in Oceania to 13.0% in North America, which may be due to surveillance differences, population risk factor profiles and availability of preventive foot care [3].

In most cases of plantar DFU, the underlying etiology is repetitive, unrecognized mechanical load placed on a foot that is also insensitive (due to peripheral neuropathy), which usually is aggravated by load concentration at particular plantar locations due to abnormal gait mechanics, structural deformity, and limited joint mobility [4]. The ulcerated foot bears weight throughout the day, and healing often occurs slowly (except when the abnormal pressure and shear stresses at the site are physically redistributed, a process known as "offloading"). Offloading is seen by numerous international consensus bodies, including the IWGDF, as a critical, non-negotiable element of the basic management of DFU, alongside debridement, infection management, and vascular evaluation [5].

A narrative review that reviews the physiological rationale for offloading, the comparative evidence of the main offloading modalities, barriers at the patient and system level for optimal offloading and introduces

novel technologies that may shape the future of offloading [6].

PATHOPHYSIOLOGY AND RATIONALE FOR OFFLOADING

The incidence of DFUs and the subsequent development of a non-healing ulcer have been shown to be associated with elevated plantar pressures, which is a well-established, independent risk factor, and pedobarography studies have consistently shown that the peak pressure and pressure-time integral at ulcer sites is higher than that on unaffected areas of the same foot [7]. With sensorimotor neuropathy the protective pain response to adapt gait is lost, and with motor neuropathy intrinsic muscle wasting occurs which can lead to claw-toe, and altered center of pressure trajectories which further increase the load over bony prominences like the metatarsal heads. Forefoot pressures are also increased during the terminal stance phase of gait by limited joint mobility in the ankle and subtalar joints as well as by Achilles tendon tightness (equinus) [8].

Barrett aims to break this pressure-injury cycle by offloading the pressure away from the injury, limiting shear forces, and—in the case of non-removable devices—actually preventing patients from taking the device off and going back to unprotected weight-bearing [9]. Cushioned total contact casting has been demonstrated to reduce the peak pressure at the ulcer site by 44% to 70% over the pressure of a standard cast shoe, and the pressure-time integral by up to 69% over the pressure of a standard cast shoe, showing the biomechanical effect that can be gained with a properly fitted device [10].

Table 1: Classification of offloading devices and their typical indications for diabetic foot ulcers

Category	Examples	Typical Indication
Non-removable knee-high	Total contact cast (TCC), instant TCC (iTCC), irremovable cast walker	First-line for neuropathic plantar forefoot/midfoot ulcers without severe ischemia or deep infection
Removable knee-high	Removable cast walker (RCW), Scotchcast boot	Second-choice when non-removable device contraindicated or not tolerated
Removable ankle-high/forefoot	Half-shoe, healing sandal, cast shoe, custom therapeutic footwear	Non-plantar ulcers, or when knee-high devices are impractical

Table 1 Continued....		
Adjunctive	Felted foam, toe spacers, digital flexor tenotomy	Third-choice/adjunct when devices unavailable or for digital ulcers
Surgical	Achilles tendon lengthening, gastrocnemius recession, metatarsal head resection/osteotomy	Refractory ulcers or Charcot-related deformity

TOTAL CONTACT CASTING: THE REFERENCE STANDARD

A close-contact, minimally-padded fiberglass or plaster cast that covers the foot and leg, evenly spread weight-bearing forces over the entire plantar surface and lower leg and eliminates shear at the wound [11]. It has been recommended as the "gold standard" offloading modality by almost all international consensus statements about DFU management since the late 1990s and clinical healing rates between 72% to 100% within 5 to 8 weeks have been reported in controlled studies. In the landmark randomized trial by Armstrong et al., 89.5% of the ulcers were healed with TCC, 65.0% were healed with RCW and 58.3% were healed with half-shoe, with mean healing time significantly shorter with TCC [12].

A systematic review and meta-analysis published in 2023 demonstrated that TCC will increase the complication rate compared to removable interventions, but will significantly improve the healing rate and healing time, with the greater incidence of skin maceration, new iatrogenic ulceration, and cast-related pressure sores the key issues [13]. This however is not removable and acts like a seal on the patient by not allowing them to take it out between visits to the clinic, thus ensuring adherence which is widely believed to be the reason that it is so successful. The efficacy of TCC is significantly less effective for midfoot and rearfoot lesions (pressure reduction of 28-49%) than for forefoot ulcers (80-90%), and is contraindicated when there is significant peripheral arterial disease, deep infection or if they are unable to tolerate cast immobilization. In-practice healing rates reported from observational cohorts (70–76%) are slightly lower than healing rates reported in trials, as they account for the natural case-mix of the patients, who may have mild ischemia, Charcot arthropathy or subclinical infection and will not heal as well. Based on

a modern retrospective cohort, the results of this study showed that treatment for TCC is still very effective in modern practice, with 80.3% achieving complete healing, and a mean healing time of 81.5 days, while non-adherence and lack of revascularization were significant factors associated with failure to heal [14].

The instant total contact cast (iTCC) was developed to maintain the adherence-enforcing benefits of the TCC while minimizing application time, cost and specialized casting skill. Randomized trials have demonstrated that the healing rate, healing time, and complication rate are similar between iTCC and TCC with iTCC needing 36-39% less application and removal time and being lower cost in material. Also, off-the-shelf devices that cannot be removed, like the Optima Diab walker, have demonstrated the same effectiveness as the traditional fiberglass casting (95% healing compared to 85% healing at 12 weeks), at significantly reduced cost and greater patient satisfaction [15].

REMOVABLE OFFLOADING DEVICES AND ADHERENCE PROBLEM

The use of removable cast walkers has practical benefits over TCC as they allow for the inspection and dressing of wounds on a daily basis, allow for bathing and do not require specialist casting technicians making it the most frequently used offloading device in general clinical practice. Well-fitted RCWs have been biomechanically shown to have reductions in plantar pressure similar to that of a TCC; but from multiple trials, there is a lack of healing benefits in the real world as patients often take them off to walk, thus cancelling out the protective benefits [16].

Non-removable fiberglass TCC showed an average healing time of about 5.4 days compared to RCW when using a rapid review and meta-analysis of five RCTs, however, this difference was largely due to adherence,

and not to the biomechanics of the device. This adherence gap is well documented by comparison studies: In one study, 82% of ulcers healed with TCC, while only 42% of ulcers healed with RCW, with the difference almost entirely due to patients' voluntary removal of the RCW during the course of daily life. Simple modifications (like sticking felt on the foot instead of on an orthotic in an RCW) have been proven to significantly increase the peak plantar pressure reduction (up to 83.1%), providing a low-cost way to improve the performance of a removable device [17].

COMPARATIVE EFFECTIVENESS: EVIDENCE SYNTHESIS

Comparison	Healing Rate / Time Difference
TCC vs RCW vs half-shoe (12 weeks)	89.5% vs 65.0% vs 58.3% healed
TCC vs removable interventions (meta-analysis)	Higher healing rate, shorter healing time with TCC; higher complication rate
F-TCC vs RCW (5 RCTs, meta-analysis)	Healing time 5.42 days shorter with F-TCC
iTCC vs RCW	82.6% vs 51.9% healed at 12 weeks; iTCC healed significantly sooner (41.6 vs 58.0 days)
iTCC vs TCC	80% vs 74% healed at 12 weeks; statistically equivalent, iTCC faster/cheaper to apply
TCC vs Optima Diab walker (off-the-shelf)	95% vs 85% healed; equivalent healing time; walker 78% cheaper
TCC vs custom-made temporary footwear	No significant difference in wound area reduction; healing time 52 vs 90 days (non-significant)
"Football" dressing (forefoot ulcers)	Mean healing time 2.91 weeks; comparable to TCC/iTCC at lower cost

In all the evidence in this base, the benefits of non-removable knee-high devices over removable devices are not due to their superior intrinsic biomechanics but are primarily related to the fact that they enforce compliance with the device in the manner in which it is

used. As seen in this evidence base, the advantages of non-removable knee-high devices over removable devices were not due to the superior intrinsic biomechanics but rather from the compliance enforced in the way the device is utilized. Lower cost, non-removable alternatives to the traditional fiberglass TCC (iTCC, off-the-shelf walkers) achieve statistically similar outcomes at lower cost and application burden [18].

INTERNATIONAL GUIDELINE RECOMMENDATIONS

The 2023 IWGDF Guideline on Offloading is an updated version of that from 2019. It offers a hierarchical set of recommendations:

Strong evidence and quality supporting information for first choice of treatment: For a neuropathic plantar forefoot/midfoot ulcer without severe ischemia or uncontrolled infection, consider a non-removable knee-high offloading device (TCC or a walker rendered irremovable) as first-line treatment [19].

For plantar or apex lesser-digit ulcers as a secondary condition of a flexible toe deformity, digital flexor tenotomy is now recommended as the first choice of treatment for this condition, with high-quality randomized trial evidence.

Removable knee-high or ankle-high offloading device with foot-device interface (with appropriate interface) is recommended for second choice treatment – when use of a non-removable device is contraindicated or not tolerated and there is an expectation of compliance by the patient.

A third choice of treatment is to ensure the correct type of footwear is used with felted foam as a minimum intervention. Surgical offloading – If non-surgical offloading has not provided relief for a plantar forefoot ulcer, achilles tendon lengthening, metatarsal head resection, joint arthroplasty or metatarsal osteotomy may be options.

SURGICAL OFFLOADING

If conservative management of offloading or ulcer has been ineffective, or if ulcers have returned despite adequate use of the device, surgical correction of the

underlying biomechanical deformity can provide a long-term solution. Preventing and treating ulcers can be difficult and may fail to heal, with equinus contracture being a major factor in this, and Achilles tendon lengthening and gastrocnemius recession have a longer lifespan than casting and orthoses alone in this regard, but with the risk of transfer ulceration at other sites [20]. There is strong randomized trial evidence for the use of digital flexor tenotomy, which is a minimally invasive outpatient procedure, specifically with plantar or apical lesser-digit ulcers associated with flexible claw-toe deformity, and is recommended as a first-line treatment in the guidelines for this ulcer subtype. Metatarsal head resection and osteotomy are reserved for ulcers that are not responsive to non-surgical offloading, and are performed to decrease the focal plantar pressure under the prominent metatarsal head.

CHALLENGES FOR OPTIMAL OFFLOADING IN CLINICAL PRACTICE

Although there is great endorsement for the guidelines, TCC is seriously underutilized in practice. Of the facilities that were surveyed, 58.1% said they didn't think that TCC is the criterion standard for offloading non-infected plantar DFUs, and only 1.7% of centers actually used TCC, with patient tolerability (55.3%), the time needed to apply the technique in the clinic (54.3%), the cost of the materials (31.6%), reimbursement barriers (27.5%) and unfamiliarity with the technique by clinicians (25%) being cited as main barriers. Other practical drawbacks are decreased mobility, inability to check the wound every day, the potential for development of additional iatrogenic ulcers under the cast, joint stiffness from prolonged cast application, and the need for specially trained personnel to apply the cast. A survey of diabetic centers in Europe also revealed that TCC was only applied in a minority of specialized centers, and that there remains a long-standing gap in evidence-to-practice [21].

The greatest problem with any removable devices is adherence at a patient level, as research has repeatedly found that patients use RCWs for only a small proportion of weight bearing activities, thus cutting their theoretical biomechanical advantage. There are several factors, such as cost, footwear compatibility, activities of daily living (such as stair use

or driving), and cosmetic concerns, that both affect adherence to removable and knee-high devices.

TECHNOLOGY: OFFLOADING OPPORTUNITIES.

Non-adherence has become a key issue for the success of removable offloading innovations, and digital health is now being directed at it. Smart insoles are an in-shoe system that contains pressure sensors which continuously measure the plantar loading and provide an audible, visual and/or vibrotactile signal to the patient on a smartwatch or mobile phone once specific pressure is reached, acting as a motivator for the patient to offload [22]. Results from a proof-of-concept randomized controlled trial showed that an intelligent insole that delivers continuous feedback resulted in a 71% decrease in the recurrence of diabetic foot ulcers after 18 months compared with a group that did not receive any feedback. A separate pilot study revealed that patients with an alert frequency of at least one alert every two hours had significantly higher adherence to offloading (52.5% vs 24.7%) and longer duration of wearing the device (8 hours vs 3.6 hours per day) than patients with lower alert frequencies, thus setting a threshold for behavioral impact.

The "SmartBoot" technology in sensor-augmented removable walkers uses an inertial sensor to determine if the walker is being worn when the patient walks, and to wirelessly send adherence data via Bluetooth to the clinic, while setting up alerts when the patient walks without the walker. The technology-acceptance study of smart offloading walkers demonstrated participants' positive ratings of the technology as easy to learn and use, and their greater desire to wear the device in the real world compared to standard removable or irremovable walkers, suggesting that smart-boot feedback may be a method to achieve greater compliance with the device without compromising the functional advantages of removability [23].

Multi-modal digital health platforms take this one step further, using continuous plantar pressure and temperature monitoring, step-counting and remote patient monitoring dashboards that alert to potentially problematic patterns (e.g., 3 days without patient using the device) that are followed up by clinicians. A recently published scoping systematic review of the 11

studies conducted so far on smart insoles and offloading sensors found that the technologies are generally seen as viable, acceptable and beneficial by patients, and that they lead to better monitoring, healing and adherence, but there is still a lack of robust and large studies for definitive trials. Other innovations being explored are 3D-printed, patient-specific insets that can be quickly and easily customized for the shape and pressure distribution of each individual's foot and devices that are not removable, but can be produced on-demand with a cast and then be priced and manufactured at an affordable cost and with less complexity [24].

Yet, the IWGDF and independent commentators point out this promise, noting that current digital offloading technologies are supported by small, short-duration studies with the need for large, adequately powered randomized trials before the tools can be formally added to first-line treatment recommendations. Other barriers to better uptake of the intervention and widespread use include cost, reimbursement and integration into existing multidisciplinary diabetic foot care workflows [25].

CONCLUSION

Knee-high devices that are unable to be removed, such as total contact casts and irremovable cast walkers, continue to be the most evidence-based, guideline recommended first-line treatment for neuropathic plantar ulcers for their ability to ensure uniform pressure redistribution at all times. Removable devices and standard footwear are still useful second- and third-line choices, although poor real world patient compliance is always a problem, which is now being addressed by lower cost irremovable alternatives (iTCC, off the shelf walkers) and more recently by sensor technology-based smart offloading devices. Surgical offloading is a long-term solution for ulcers which are not treated conservatively or for fixed biomechanical deformity. Underuse of non-removable casting in routine practice due to cost, training, and workflow barriers is an important evidence-practice gap that needs to be addressed in future implementation research, and as digital health tools develop.

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AUTHOR CONTRIBUTIONS

Raihana Thazmeen: Conceptualization, literature search and screening, manuscript drafting, critical revision of the manuscript, and final approval of the version to be published.

Aakash J: Literature search, data extraction, drafting of sections of the manuscript, and review of the final draft.

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Akash Harikrishnan: Literature search, data extraction, drafting of sections of the manuscript, and review of the final draft.

Thireeshith GS: Literature search, data extraction, drafting of sections of the manuscript, and review of the final draft.

All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

ABBREVIATIONS USED IN THE STUDY

DFU: Diabetic Foot Ulcer

DFUs: Diabetic Foot Ulcers

NLLA: Non-Traumatic Lower-Limb Amputation

IWGDF: International Working Group on the Diabetic Foot

TCC: Total Contact Cast

iTCC: Instant Total Contact Cast

RCW: Removable Cast Walker

RCWs: Removable Cast Walkers

RCTs: Randomized Controlled Trials

F-TCC: Fiberglass Total Contact Cast

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