



Offloading in ulcer prevention and its relapse

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Article points

1. Identify and analyse trauma-related causal factors.
2. Critically review any interventions regularly and audit outcomes.
3. Patient involvement in decision making is essential.

Key words

- Initial and relapse ulcers
- Offloading/Force management
- Prevention

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The term “offloading” is generally given to techniques employed in the treatment of active foot ulceration or immobilisation of acute Charcot neuroarthropathy. It can equally be used for modalities and strategies for the prevention of new and relapse ulcers. In this context, perhaps the term “deleterious force management” would be better suited. Preventing the first ulcer is the ultimate goal of risk screening and stratification thus understanding the mechanisms for ulceration should direct clinicians to employ timely and appropriate offloading strategies. The rate of ulcer relapse is very high with reported rates of 40% in 4–12 months and 70% in 3 years. Managing healed ulcers is complex and requires considerable understanding and sustained activity. Central to all of this is active patient involvement and unhindered, easy access to foot protection teams, as well as adequate resource allocation. It is the authors’ view that sadly perhaps more focus is placed upon ulcer healing rather than preventing relapse. This article will briefly explore the area of “offloading” in the prevention of ulceration and its relapse. When reading this article, it would be useful to bear in mind some of the concepts that were previously discussed in the authors’ article in *The Diabetic Foot Journal* 19(4), ‘The principles and practicalities of offloading diabetic foot ulcers’.

It is well known and documented that foot ulceration is perhaps the most common and serious long-term complication of diabetes. Within the UK, patients with diabetes should be seen on an annual basis for a diabetes review. As part of this process, feet ought to be screened and stratified for ulceration risk using well-determined risk factors. Prevention is paramount given that published data suggest that up to 25–90% of lower-extremity diabetes-related amputations are preceded by foot ulcers (Pecoraro et al, 1990; Global Lower Extremity Amputation Study Group, 2000). Determining ulcer risk is clearly important, however, the implementation of individualised prevention strategies is pivotal, if success is to be achieved. The focus of this article, is to discuss the role of offloading in preventing the first ulcer and/or relapse.

As the published evidence for offloading and ulcer prevention is meagre, a review of such would not be very helpful. Therefore, this article will provide

a practical and clinical view of the way in which offloading can be beneficial in ulcer prevention. The overriding caveat is that prevention is only successful when it is implemented and regularly reviewed by both practitioners and patients alike.

As stated above, the first steps in ulceration prevention are identifying those who are at risk and then stratifying ulcer risk for each patient. The next stage is facilitating access to differing levels of diabetic foot-care commensurate with an individuals’ risk. For those at medium to high risk, the keys to success in preventing a foot ulcer is two-fold. Firstly, clinicians should equip patients and/or their carers with repeated, clear, simple, targeted and tangible education. Secondly, the patient should be offered an adequate, specialised, well-organised and easy accessible service with a dedicated diabetic foot care team. Staff within these should be enabled to recognise the very early subtle signs of tissue damage, identify their causes and implement

directed interventions. Obviously, tissue damage can occur at any time during activity periods or, in the case of pressure sores, during protracted rest. Thus, educating patients to recognise and respond to ulceration danger signs and symptoms together with how/when to access services is vital if prevention is to be achieved.

Before exploring the different preventative offloading modalities and their implementation, it is wise to firstly consider two fundamental topics:

- The mechanism of ulceration
- What do we mean by “offloading”?

Ulceration overview

It is important that clinicians take a step back and consider what processes are involved in developing a diabetic foot ulcer. Unless these processes are clearly understood from a clinical perspective, ulcer prevention will most likely only be achieved by chance. It is essential to translate classroom-taught theory into clinical practice. Additionally, to understand or conceptualise the interactions and reactions of normal/altered physiology and pathomechanics. To illustrate this thought process, consider one aspect of what happens to soft tissues under the third metatarsal head in a normal foot during walking. The tissues in this area should be considered as they are about to be fully loaded.

In *Figure 1*, some of the forces that are applied to the metatarsal head during gait are displayed. The reader should consider and try to visualise the magnitude, duration, velocity and direction of these, as they will change throughout this localised loading cycle. *Figure 2* shows a very simplified view of some of the soft tissue reaction to full loading. As the foot moves forward, the footwear and ground moves back. With this in mind, picture rotational shear and compressive forces applied to the tissues, not just directly under, but also surrounding the metatarsal head. Now add in the frictional force applied over these stretched, twisted and squashed tissues. Lastly, consider the components of time, velocity, magnitude of internal/external loading and changing direction of these forces.

Normal healthy soft tissues are able to withstand this assault predominately due to their visco-elastic nature. The blood vessels are also able to accommodate these effects without rupturing. Of course, if the nature or magnitude of these become

Force considerations	Intervention considerations
Low pressure + time leads to tissue anoxia and death by occluding capillary blood flow	These are typically heel sores. Reduction of pressure is insufficient — total pressure relief is absolutely essential for resolution and minimising tissue loss
Moderate force + persistent sustained repetition leads to inflammation	Biomechanics and casual management is key. Footwear, insole design and skin temperature self-monitoring is important
Repeated sustained inflammation without rest leads to inflammatory autolysis. The common clinical presentation of this is blood staining in plantar callus	Callus formation is due sustained skin inflammation. Shear and friction force management. Footwear fastenings, callus reduction and skin hydration
Repeated or sustained force + infection leads to spreading sepsis	Encouraged or enforced rest/offloading while acute, early or uncontrolled infection periods. Use of removable cast walkers may be of benefit

Pre-ulceration stage	Post-ulceration stage
Therapeutic stock shoes	Therapeutic stock shoes
Simple flat insoles	Adapted therapeutic stock shoes
Total-contact/custom moulded insoles	Bespoke made-to-measure footwear
Callus reduction	Simple flat insoles
Education	Bespoke total-contact or moulded foot orthoses/insoles
	Surgery

too much, neural responses are evoked, i.e. pain and soreness leading to alterations in gait, whereby offloading and, thus, protection of the tissue prevents tissue damage.

Apply the above to a person with diabetes, then add peripheral neuropathy and impaired blood flow. Below are some points for consideration regarding the effects upon soft tissue mechanics. These are very important, with some more subtle than others, but resultant tissue failure is often manifested and observed in the skin. The authors believe that addressing these effectively is integral in preventing the progression of pre-ulcers to ulceration:

- Glycation of soft tissues — stiffer with loss of visco-elasticity
- Altered rheology (blood flow dynamics)
- Stiffer, less elastic or more fragile blood vessel walls
- Loss of protective sensation and or proprioception
- Altered muscular/articular mechanics



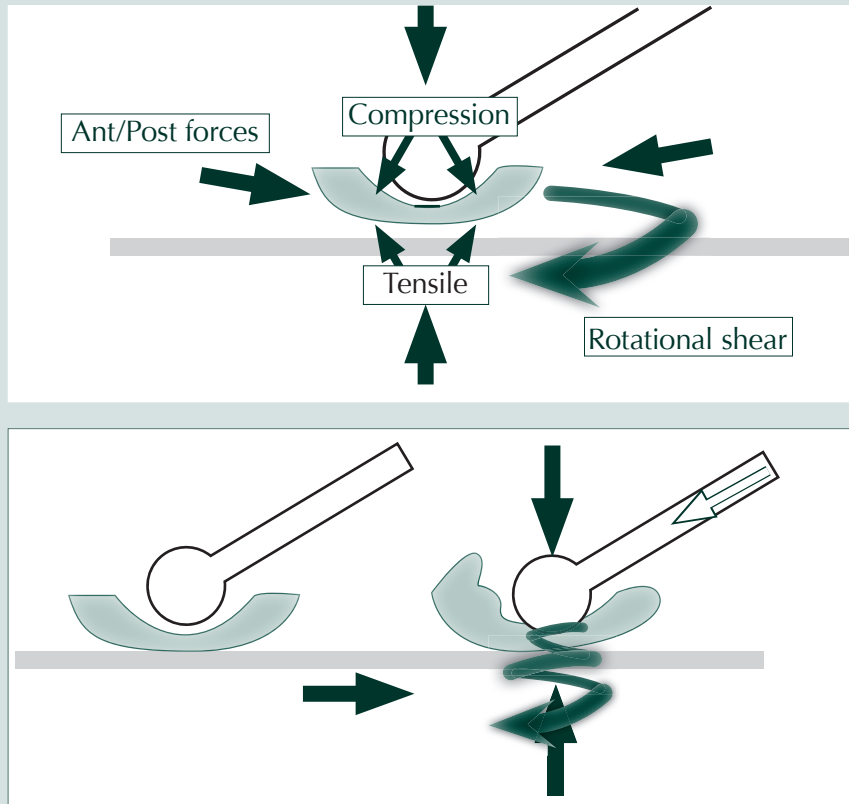


Figure 1 (top). A simplified diagram to show the different forces applied to a metatarsal head during standing and walking. Figure 2 (above). A simplified diagram showing soft tissue deformation over a metatarsal head at the propulsive phase of gait.

- Diminished/absent skin hydration
- Reduced or increased inflammatory responses.

The above list details the components in the pathway to tissue damage and potential ulceration. Understanding each component and their influence upon each other and their relation to tissue damage is essential to help drive successful preventative interventions. Thus, simply arranging regular follow-up visits with a podiatrist to reduce plantar callus formation in a patient with peripheral neuropathy should be considered suboptimal ulcer prevention.

Ulcer relapse considerations

Definition: ulcer relapse is a second or subsequent ulcer occurring at a previous ulcer site.

It is well documented that the highest risk factor for ulceration is a previous ulcer. The literature cited ulcer recurrence/relapse as high as 30–40% within 12 months (Pound et al, 2013; Bus et al, 2013), as opposed to an annual incidence of 7.5% for first ulcers in patients with neuropathy (Abbott et al, 2002). There are reasons why ulcer relapse rates are higher than for new ulcers and identifying these is paramount if prevention is to be achieved. Several

causes for ulcer relapse that have been suggested, including inadequately addressed existing first ulcer aetiologies, e.g. neuropathy, deformity, high plantar pressures, etc. or, delays in providing prescribed footwear (Bus and van Netten, 2016). Additionally, the failure of healthcare professionals to provide recommended treatment, including foot care, therapeutic footwear, and patient education (Lavery et al, 2010), patients not following foot care advice or wearing prescribed shoes (Waijman et al, 2013).

However, while these causes are credible, it is the authors view that perhaps the most important reason for ulcer relapse is being overlooked. As stated above, non-ulcerated foot soft tissues are visco-elastic and have very specifically biomechanical properties designed to accommodate walking and standing. However, scar tissue at a healed ulcer site is fairly rigid with dramatically altered soft tissue mechanics in this and surrounding tissues. In short, the repaired tissue is even less able to withstand the forces that caused the original ulcer. Moreover, each subsequent time an ulcer relapses and repairs, it becomes less and less able to withstand them, thus leading to high ulcer relapse rates.

It is even more important to appreciate the forces applied to the foot when considering offloading strategies to prevent ulcer relapse. Focusing resources upon these may prove successful, however, little data are available to substantiate this approach.

“Offloading”: what do we mean?

The term “offloading” is principally one that is associated with foot ulcer management or pressure sore treatment/prevention. The main method in ulcer management is to immobilise the foot and ankle by use of either casts or removable walker boots. However, this is not practical in ulcer prevention strategies as this approach dramatically curtails everyday activities including employment. Thus, offloading in the prevention of first ulcers or their relapse would be better described as “lesion preventative force management”. The principal is similar in one broad respect, i.e. to relieve tissue damaging forces applied to the foot whereby preventing tissue damage.

Offloading interventions and practices are used worldwide in many different settings. Some have been studied, including foot screening, treatment of pre-signs of foot ulceration, footwear advice, and foot-care

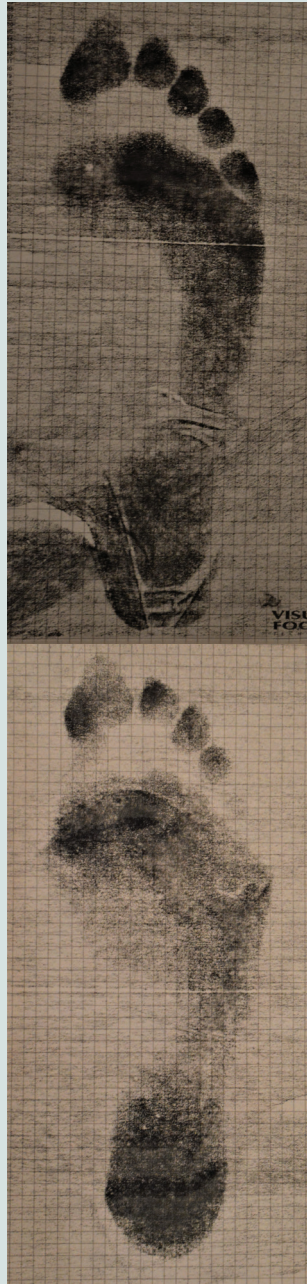


Figure 3 (top). A barefoot pressure print — note the dark areas are high pressure points. These are at second and fifth metatarsal heads, toe tips and big toe.

Figure 4 (above). This is what happens to the high-pressure areas when a felt pad is used.



Figure 5. Shows a semi-compressed felt pad to reduce pressure over fifth metatarsal head area.

education, these are reported in the the International Working Group on the Diabetic Foot (IWGDF) Guidance on Prevention (Bus et al, 2016). However, the use of these interventions is based on low quality of evidence or expert opinion rather than good quality research evidence.

Footwear

There have been several prospective studies that have shown that therapeutic footwear compared with standard footwear can help prevent ulcer relapse (Uccioli et al, 1995; Litzelman et al, 1997; Dargis et al, 1999; Viswanathan et al, 2004).

The rationale for providing a protective environment for feet in order to prevent new ulcer occurrence makes perfect sense, but the body of evidence to support this is currently poor. It is confounded by the fact that most studies combine new and recurrent ulcers in their study populations. One study provided intensive footwear therapy versus standard care with footcare advice, but no prescribed shoes. This showed an incidence of foot ulceration of 11.5%, 17.6% and 23.5% at 1,3 and 5 years respectively in the intensive footwear therapy group, compared with 38.6%, 61% and 72% for 1, 3 and 5 years in the group that was not prescribed shoes. One fifth of the cohort had a history of ulceration (Rizzo et al, 2012). A small cohort study found no difference in ulcer occurrence between those wearing prescribed shoes versus those who wore their own (Reike et al, 1997). However, another study comparing prescribed shoes group versus a normal shoe group showed an ulcer recurrence rates

of 15% versus 62% respectively over 2 years (Busch and Chantelau, 2003).

Thus, from a few selected studies it is clear to see the discrepancies, which are probably due to study bias and poor study design. Equally, it is difficult to identify from the literature what the most effective features of a shoe and/or foot orthosis design are. Some features including rocker-bottom soles, custom-made insoles and some shoe inserts (e.g. metatarsal pads and medial arch supports) may reduce forefoot peak pressure between 16% and 52% compared with controls (Schaff and Cavanagh, 1990; Lord and Hosein, 1994; van Schie et al, 2000; Praet and Louwerens, 2003; Bus et al, 2004; Beuker et al, 2005; Guldmond et al, 2007). The design of foot orthoses, including the choice and combination of materials, requires considerable thought. In addition, regarding therapeutic shoes, determining the placement, size and angle of rocker sole is critical. When reflective consideration is given to these factors together, ulcer prevention is achievable. However these decisions in reality are more guided by clinical experience of preference than available robust research evidence. Incorrectly designed footwear can increase ulcer risk rather than reduce it.

The evidence base for footwear in the prevention of new and relapse ulcers is very useful even if the quality of this research is poor (Bus et al, 2008). Arguably, however, even if the current research quality was good, it is only partly useful. Patients are mainly older and weight-bearing activity occurs mainly indoors. Several articles also point to this; existing activity data of ulcer patients show they are less active than non-ulcer patients (Armstrong et al, 2001; Maluf and Mueller, 2003) and spend more time indoors (Armstrong et al, 2001). Regarding prescribed footwear, the authors' experience has been that many patients will not wear their prescribed shoes or special insoles while indoors, preferring to wear slippers or nothing instead. This is another reason why ulcer relapse rates may be so high.

Other strategies

Callus

Callus formation is the skins protective response to abnormal and potentially harmful applied force. Excessive callus formation in patients with sensory loss has been shown to be an ulcer risk factor and its reduction can cut plantar pressures by up to 30%, although the durability of such relief is unknown

(Young et al, 1992; Pitei et al, 1999). Providing silicone digital orthoses, soft insoles, debridement and extra depth footwear demonstrated a reduction in ulcer rates, but also callus growth compared with control groups (standard care comprised of debridement, extra depth shoes and a flat cushioning insole) of 1.1% and 15.4% for ulcers and 51% versus 84% callus suggesting intervention benefit (Scire et al, 2009). It cannot be overemphasised that regular reduction of plantar callus is essential, however, understanding and addressing its causes needs equal attention.

Felt padding

One recent study showed that adding semi-compressed felt to footwear to offload high-risk sites on the foot reduced peak pressure by 50% immediately and after one week there was still a 33% reduction (Raspovic et al, 2016). This technique,

which has been used in podiatry for many years, is perhaps useful as a quick temporary method of offloading. Its effect is shown in *Figures 3,4 and 5.*

Skin temperatures

The use of infrared thermometers to measure skin temperatures on a daily basis to identify hot spots followed by periods of rest has been studied. This has been shown to be of benefit in helping to prevent foot ulceration (Armstrong et al, 2007; Lavery et al, 2004; 2007). This patient-mediated reactive offloading may be very useful as part of an ulcer relapse prevention programme it can be implemented and sustained by patients.

Soft tissue augmentation

As already stated, once an ulcer has healed, the resultant scar tissue is functionally unable to deal with the damaging forces that caused the initial ulcer.

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Thus, any modality that can restore, mimic or, better still, enhance the original soft tissue function would be perhaps the most effective way of preventing ulcer relapse. The use of injected liquid silicone has been used to achieve this with some success, but more investigations are required in this field (van Schie et al, 2002).

Education

The authors of a recent Cochrane review stated that it appears there is little evidence available to support the effectiveness of patient education for ulcer and amputation prevention (Dorresteijn et al, 2010). While this is disappointing, it is not surprising, especially in light of a recent study by Natovich (2016) that showed cognitive impairment in those with neuropathic foot ulcers suggesting an inability to learn or apply health education as it is currently delivered. Empowering patients with not only understanding, but also necessary skills to identify and react to tissue damage, is fundamental if prevention strategies are to be successful.

Surgery

Another approach for offloading is to remove or alter any bony prominences over ulceration sites or reduce soft tissue restrictions in selected patients. Achilles tendon lengthening, single or pan-metatarsal head resection and metatarsophalangeal joint arthroplasty in patients with previously recalcitrant ulcers seem to reduce ulcer relapse compared with non-surgical treatment (Piaggese et al, 1998; van Schie et al, 2002; Armstrong et al, 2003; 2005; 2012; Mueller et al, 2003; Dorresteijn et al, 2010; Natovich et al, 2016). Additionally, osteotomies may also reduce ulcer relapse (Downs and Jacobs, 1982; Lin et al, 2000). However, consideration must be given to surgically induced altered foot mechanics. If force is removed or reduced from one area it must be relocated elsewhere.

Conclusion

In conclusion, offloading or force management used for the prevention of first and relapse ulcers makes perfect sense, however it is difficult to draw any clear directions from the research evidence base. This is in part due to a lack of well-designed prevention studies solely dedicated about this topic. Despite this “offloading” is an important facet of care in preventing diabetic foot ulcers. It is only really

effective when underlying aetiological pathways of tissue failure are understood as this can be used in formulating offloading strategies and modalities. In this area, as well as in all diabetic foot management integrated team work is essential to achieve successful outcomes. ■

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1. What is the COSTLIEST long-term complication of diabetes? Select ONE option only.
 - A. Cerebrovascular disease
 - B. Foot ulceration
 - C. Ischaemic heart disease
 - D. Peripheral neuropathy
 - E. Visual impairment

2. When walking, which SINGLE mechanical force, if any, is MOST likely to cause diabetic foot ulceration? Select ONE option only.
 - A. Compressive
 - B. Frictional
 - C. Rotational
 - D. Vertical
 - E. No single force more likely

3. Which clinical problem is BEST defined by the term 'abnormal rheology'? Select ONE option only.
 - A. Absent skin hydration
 - B. Altered blood flow
 - C. Diminished sensation
 - D. Glycation of soft tissue
 - E. Reduced proprioception

4. A 79-year-old man with type 2 diabetes has a low-pressure heel ulcer. Which is the SINGLE MOST appropriate INITIAL management? Select ONE option only.
 - A. Callus reduction
 - B. Compression hosiery
 - C. Felt pads
 - D. Removable cast walker
 - E. Total pressure relief

5. Which risk factor has the HIGHEST association with subsequent diabetic foot ulceration? Select ONE option only.
 - A. Abnormal gait
 - B. Peripheral arterial disease
 - C. Peripheral neuropathy
 - D. Poor glycaemic control
 - E. Previous foot ulcer

6. A 45-year-old man has type 1 diabetes and peripheral neuropathy. He has no previous history of foot ulceration. According to Abbot et al (2002), what is his ESTIMATED annual risk of developing a first diabetic foot ulcer? Select ONE option only.
 - A. 2.5%
 - B. 7.5%
 - C. 15%
 - D. 25%
 - E. 50%

7. An 89-year-old nursing home resident has type 2 diabetes and vascular dementia. She has high-risk sites on both second toes. Which is the SINGLE MOST appropriate INITIAL management? Select ONE option only.
 - A. Custom made insoles
 - B. Felt padding
 - C. Monitor skin temperatures
 - D. Patient education
 - E. Silicone fluid injection

8. According to Baker and Cundell (2017), which factor related to diabetic foot ulcer relapse is MOST LIKELY to be overlooked? Select ONE option only.
 - A. Foot deformity
 - B. High plantar pressure
 - C. Peripheral arterial disease
 - D. Peripheral neuropathy
 - E. Rigid scar tissue

9. According to current evidence, which is the SINGLE MOST effective footwear, if any? Select ONE option only.
 - A. Custom made insoles
 - B. Medial arch supports
 - C. Metatarsal pads
 - D. Rocker-bottom soles
 - E. The evidence is unclear

10. A 51-year-old woman with type 2 diabetes has had a recent foot ulcer which has now fully healed. According to Pound et al, 2013 and Bus et al, 2013, what is the ESTIMATED LIKELIHOOD of her ulcer recurring within 12 months? Select ONE option only.
 - A. 10%
 - B. 25%
 - C. 33%
 - D. 50%
 - E. 66%