Pressure and the diabetic foot: clinical science and offloading techniques

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Abstract

Diabetic foot ulceration is a common, yet in many cases an eminently preventable, complication that affects 1 in 20 patients with diabetes. Risk factors for ulceration include insensitivity (secondary to somatic neuropathy), high foot pressures, callus formation (a consequence of sympathetic neuropathy and high foot pressures), deformities (such as claw feet, prominent metatarsal heads, etc.), peripheral vascular disease, and most importantly, a past history of ulceration. None of these factors alone causes ulceration; thus, early identification and amelioration of these factors is a primary aim in foot ulcer prevention. A number of therapeutic approaches may help reduce ulcer incidence: these include therapeutic footwear, hosiery, and, potentially, liquid silicone injected under high-pressure areas. In the management of neuropathic ulcers, pressure relief is of the utmost importance, and total contact casting remains the “gold standard” means of achieving such pressure redistribution. The successful management of diabetic foot ulceration depends on a team approach, remembering that ulcers should heal if (1) the arterial circulation is intact, (2) pressure relief is achieved and maintained over the ulcer, and (3) infection is appropriately treated. © 2004 Excerpta Medica, Inc. All rights reserved.

I marvel that society would pay a surgeon a large sum of money to remove a person’s leg—but nothing to save it.
—George Bernard Shaw

The aims in treating diabetic foot problems should primarily be concerned with limb preservation when at all possible. In this regard, pressure applied to the foot is vitally important at every stage in the causation and management of diabetic neuropathic foot lesions: that is, in primary and secondary prevention, as well as in the treatment of active ulcers and acute Charcot neuroarthropathy. The need for a better understanding and treatment of diabetic foot ulceration is strongly supported by the literature as well as by depressing statistics: trends in amputations show no overall signs of improvement [1–3], and foot ulceration is the most common reason for hospitalization of diabetic subjects in many countries [4]. In this review, the main contributory factors in the etiopathogenesis of diabetic foot ulceration will be considered, with special emphasis on the role of foot pressure abnormalities. Potential approaches for the reduction or redistribution of pressure will be discussed. Finally, the need for and methodology of pressure reduction as part of the treatment of neuropathic foot ulceration will be considered.

The pathway to diabetic foot ulceration

Coming events cast their shadows before.
—Thomas Campbell

The problems related to the pathogenesis of diabetic foot ulceration are summarized by the words of the Scottish poet Thomas Campbell. Diabetic foot ulceration is very common, affecting 1 in 20 patients with diabetes at some time during their lives. The “coming event” of a foot ulcer can in many cases be predicted by identifying the “shadows” or warning signs that appear in many patients with diabetes at high risk of ulceration. Foot ulceration invariably occurs as a consequence of an interaction between environmental hazards and specific pathologies in the lower extremities of these patients. Peripheral vascular disease is of course much more common in this population, but in terms of prevention, it is the neuropathic or neuroischemic ulcer that provides the most scope for prevention.

Diabetic neuropathy

Diabetic neuropathies are among the most common of all diabetic complications, appearing in up to 50% of older
patients with type 2 diabetes [5,6]. Of the various neuropathic subgroups, it is distal sensory polyneuropathy and peripheral autonomic dysfunction that are most associated with risk of foot problems. Distal sensory polyneuropathy is extremely variable in its presentation, ranging from the severely painful symptomatic variety at one extreme to the completely painless variety at the other, which may present with insensitive foot ulceration. Indeed, up to 50% of patients with neuropathy never experience symptoms, so absence of neuropathic symptomatology must never be associated with absence of risk of foot ulceration (Fig. 1). The “at-risk” foot can be identified only by a careful clinical examination for loss of sensation to large and small fiber functions (for example, vibration and pinprick sensation) and absence of ankle reflexes. A large community-based project in northwest England, the Northwest Diabetes Foot Care Study [7], has recently confirmed in a prospective follow-up of almost 10,000 patients that a simple clinical examination, such as that noted above, is highly predictive of risk of foot ulcers. Those with a moderate or severe deficit on clinical examination had a 6-fold increased risk of developing ulceration, compared with those with normal sensory function [7]. Peripheral autonomic dysfunction results in increased peripheral blood flow in the absence of
large vessel obstructive vascular disease, together with dry skin because of the absence of sweating. Thus, the warm, dry, insensitive foot is at high risk of ulceration.

The strong association between peripheral neuropathy and foot ulceration has been recognized for many years [8], but it was not until the last decade that this was confirmed in prospective studies. A single-center study demonstrated that neuropathic patients had a 7-fold annual increase in the risk of ulceration, and this earlier report was confirmed in a larger multicenter study from Europe and North America, which showed that those with neuropathy had a 7% annual risk of developing foot ulceration [9,10].

**Foot pressure abnormalities in diabetes**

The insensitive diabetic neuropathic foot does not ulcerate spontaneously: traumatic ulcers result as a consequence of trauma to the insensitive foot, as in the patient who purchases shoes of an insufficient size and fails to experience any discomfort while wearing them. This constantly maintained pressure leads to breakdown of the skin at the site of highest pressure, usually the lateral border of the fifth or first metatarsal head.

In contrast, pressure ulcers occur as a result of pressure that would not normally cause ulceration, but which, because of intrinsic abnormalities of the neuropathic foot, leads to plantar ulceration when applied repetitively. Abnormalities of pressures and loads under the diabetic foot are very common, as has been shown in several cross-sectional studies [11,12]. Thus, the combination of insensitivity, abnormally high foot pressures, and repetitive stress from, for example, walking may lead to breakdown under high-pressure areas, such as the metatarsal heads. In a prospective study, Veves et al [13] observed a 28% incidence of ulceration in neuropathic feet with high plantar pressures during a 2.5-year follow-up period; in contrast, no ulcers developed in patients with normal pressure. Thus, biomechanics, the branch of science concerned with the consequences of forces applied to living tissues, is clearly relevant to diabetic foot disease because the majority of neuropathic foot ulcers result from mechanical stress that is not perceived by the patients. The repetitive application of high pressures to the same soft tissue sites overlying a bony prominence in the absence of protective sensation is believed to cause tissue damage, which begins deep and initially may not be visible on examination. However, callus tissue frequently forms at the surface, which is a cutaneous marker for high pressure. Before ulceration, hemorrhage into the callus occurs; this should be recognized as a "preulcerative" lesion [14] (Fig. 2). In a separate observational study, Murray et al [15] reported that the increased risk of ulceration in an insensitive foot with a callus was 77-fold, whereas in the prospective follow-up, ulceration occurred only at sites of callus.

A number of methodologies are available to assess plantar pressures: these devices may assess barefoot or in-shoe plantar pressures, and all usually require the use of a computer together with software. Optical systems include the optical pedobarograph (Fig. 3), whereas the majority of methodologies use a matrix of transducers [16,17]. All these systems are necessarily expensive and require trained personnel and a gait laboratory. More recently, a semi-quantitative estimation of pressure distribution known as PodoTrack (A. Algeo Ltd., Liverpool, UK) or PressureStat (FootLogic, New York, NY) has been reported. This is based on the original Harris mat technique, and comprises a 3-layer sandwich on which the patient’s foot leaves an impression in different shades of gray. Thus, this is a portable, inexpensive, and disposable method for semiquantitative assessment of pressure under the foot. After walking across this mat, plantar pressure can be assessed by visual comparison between the grayness of the foot print and a calibration card [17]. In a comparative study with the pedobarograph, the PodoTrack identified all high-pressure areas, suggesting that this could be a useful screening tool to identify areas at risk of ulceration in patients with diabetes [18].

More recently, techniques have been developed to assess the depth of subcutaneous tissue under high-pressure sites, such as the metatarsal heads. One such technique uses ultrasound to determine depth while standing [19]. In a large cross-sectional study, Abouaesha et al [20], using the PlanScan (Toshiba Medical Systems Europe, Zoetermeer, Netherlands) ultrasound technique, demonstrated a significant inverse correlation between peak plantar pressures and plantar tissue thickness at all metatarsal heads. Thus, high pressures are associated with reduced subcutaneous tissue depth, and the simple assessment of subcutaneous tissue depth by ultrasound may be an alternative method of identifying areas at high risk of ulceration.

**Other risk factors for foot ulceration**

Several studies have confirmed that foot ulceration is most common in those patients with a past history of ulceration, amputation, or Charcot neuroarthropathy. This risk may be as high as 50% of patients with new foot ulcers who have a past history of similar problems [8].

Patients with other complications of diabetes, including retinopathy and/or renal impairment, are at increased risk of ulceration. In contrast, patients from certain racial or ethnic backgrounds, including Indian subcontinent Asians, seem to be at reduced risk of ulceration. This may be related to better foot care in certain religious groups, but it is not related to geographical differences [8]. Finally, any deformity occurring in the diabetic foot, such as prominence of metatarsal heads, clawing of toes, Charcot deformities, or hallux valgus, increases ulcer risk.

An understanding of all these contributory factors that ultimately result in foot ulceration is likely to help in the planning of effective preventive strategies. In a 2-center (US/UK) study assessing causal pathways to foot ulceration...
[21], neuropathy was the most common component cause in the pathway. According to this study, the most common causal pathway leading to ulceration involved a combination of neuropathy (resulting in insensitivity), deformity (such as claw toes or prominent metatarsal heads), and trauma (most commonly resulting from inappropriate footwear; Fig. 4).

Prevention of foot ulceration

A number of therapeutic approaches to “offload” or redistribute high pressure have been reported in the last 10 years.

Therapeutic footwear

The use of therapeutic footwear is certainly not a new approach: examples of footwear worn by Roman soldiers can be seen at Hadrian’s Wall Museum in northern England. Although it is well recognized that inappropriate footwear is a very common component cause in the pathway to foot ulceration, until recently, footwear design has been more of an art than a science. In a systematic review of foot ulcer prevention for patients with type 2 diabetes, Mason et al [22] found only 1 controlled study that had assessed the efficacy of therapeutic shoes to reduce ulcer incidence. In a randomized study of 69 patients with previous ulcerations,
Fig. 3. The printer output for 1 footstep recorded from a patient with neuropathic diabetes’ previous foot ulcer under the first metatarsal head region, left foot. Ten sample frames from the footstep are shown on the left from heel strike (top left) to the lift-off phase of the footstep (bottom middle). The composite image for the whole footstep is shown (top right), along with a graph of pressure versus time for selected areas of interest (bottom right). Note the very high pressures found under the first metatarsal head, particularly toward the end of the footstep.

Fig. 4. Pathways to diabetic foot ulceration. The classic pathways to foot ulcers are demonstrated here, but increasingly patients with postneuropathy and vascular disease are presenting with neuroischemic ulcers.
Uccioli et al [23] reported significantly fewer recurrent ulcers in those wearing therapeutic shoes rather than their normal footwear. This study therefore suggested important health benefits from appropriately designed footwear. Other reports have confirmed the importance of footwear as part of a multidisciplinary approach, including regular podiatry, foot clinic visits, and so on [24].

It should also be remembered that the vast majority of patients at risk for foot ulcers can be successfully managed either in over-the-counter sports shoes, such as sneakers, or in extra-depth shoes with prescribed flat or customized insoles [14]. Appropriate footwear should provide cushioning or relief of pressures at sites of elevated pressure and might also transfer load from one site to another. For detailed discussion of the use of footwear and insoles to offload high-pressure areas, the reader is referred to detailed reviews by Cavanagh et al [14,17].

**Hosiery**

Protective padded hosiery has been shown in a prospective study to reduce high foot pressures that are known to be associated with the genesis of foot ulceration [25]. A subsequent longitudinal study conducted in the United States confirmed that such protective hosiery had a high level of patient satisfaction when worn with suitable shoes, and thus appears to be an acceptable and inexpensive addition to existing methods of protecting the high-risk, insensitive diabetic foot [26].

**Injected liquid silicone**

As noted above, foot ulceration frequently occurs at sites of higher plantar pressure and callus formation under the metatarsal head region of the insensitive neuropathic foot. Indeed, the removal of plantar callus has previously been shown to reduce abnormally high foot pressure under the metatarsal heads [27] and therefore probably to reduce the risk of ulceration. Previous uncontrolled reports from California had suggested that the therapeutic use of liquid silicone injections in the foot to replace the fat padding at callus sites, corns, and localized painful areas led to a reduction in callus formation and foot ulcer occurrence [28].

More recently, a randomized controlled trial investigated the effectiveness of liquid silicone injections in the diabetic foot and confirmed that those patients receiving silicone injections had significantly increased plantar tissue thickness at injected sites compared with the placebo group, as well as correspondingly significantly decreased plantar pressures. Such benefits were maintained for up to 12 months of follow-up. A trend was also noted toward a reduction of callus formation in the silicone-treated group compared with no change in the placebo group [29]. Further analyses of the results in this study suggest that the patients most at risk of ulceration (ie, those with highest foot pressures and lowest subcutaneous tissue thickness) are likely to respond best to treatment of injection of liquid silicone in the plantar surface of the foot [30]. These preliminary data suggest the potential efficacy of plantar silicone injections, which appears to be safe and without side effects [29,30].

**Management of neuropathic foot ulceration**

Offloading of high-pressure areas in the neuropathic foot is a key step in the management of ulceration. Many methods have been suggested, and these include bed rest, wheelchair, crutches, total contact casting (TCC), felted foam, half-shoes, therapeutic shoes, cast walkers, and so on [31]. The first 3 on this list theoretically should be very effective but rarely work in practice. It must be remembered that patients with insensitive feet have lost their warning signal, pain, which ordinarily prevents them from walking on an ulcer. The care of the patient with no pain sensation is a challenge for health care professionals, few of whom have any training in this area. It is difficult for us to understand, for example, that an intelligent patient with an active ulcer may rest in bed for the first day but then take a small step, find that there is no discomfort, and soon get back to normal activities. It is therefore important to understand that if we are to succeed, we must realize that with loss of pain there is also diminished motivation in the healing of injuries. This is among the main reasons why, of all the items listed as offloading modalities, it is TCC that is accepted as the “gold standard.”

**Casting**

A number of casting techniques have been used in the management of neuropathic foot ulceration, with the earliest studies being performed in patients with leprosy (Hansen disease). However, the use of casting has been supported by 2 randomized trials. In the first of these, Mueller et al [32] randomized 40 patients to either traditional treatment or TCC and demonstrated that significantly more ulcers healed with fewer infections in the TCC group. More recently, Armstrong et al [33] compared TCC with a removable cast walker and a half shoe in a randomized, controlled trial. The proportion of healing was far greater for those with TCC treatment, with 90% of patients being healed within 12 weeks of casting. During this trial, all patients were provided with an activity monitor, a device that measures the number of steps taken over a period of time and records the time that each step is taken. A further observation from this study was that those treated with TCC were significantly less active, with 600 daily steps compared with >1,400 daily steps taken by those in the 2 other treatment groups. As a consequence of this study, Armstrong et al performed a further observational study in which patients with diabetes and a high risk of recurrent ulceration were dispensed a continuous activity monitor and a diary to record where steps were taken. An interesting finding from this study was...
that although 85% of patients wore the approved footwear most of the time while they were outside the home, only 15% continued to wear it at home. Because patients also took more steps per day inside their homes, it appears that future preventive education should focus on protection of the foot during in-home walking [34]. Indeed, activity-monitoring studies [35] have suggested that we might consider “dosing” activity as we dose a drug—that is, restricting mobility during periods of active ulceration and in the early phases of rehabilitation after foot ulcers have healed.

The contributory factors to the efficacy of TCC treatment are likely to be, first, that there is pressure redistribution and offloading of the ulcer area, and second and possibly equally important, that the patient is unable to remove the cast, thereby enforcing compliance and reducing activity levels. A number of other casting techniques are often used and include the removable Scotchcast boot (fiberglass cast boot; 3M, Maplewood, MN), where a window is cut under the ulcer area and the cast. The cast gives support up to ankle level and may be removed at night. Walking is permissible with a walking sandal. Such casts have been successfully used in several centers.

Other modalities

A number of approaches to offloading foot ulceration have been described [36] and include a number of different casting techniques and also the use of a half-shoe in the healing of forefoot plantar ulcers in Germany [37]. These shoes support only the rear and mid foot, leaving the forefoot “suspended” in mid air. A number of different orthotic devices have also been described, as discussed by Cavanagh et al [17]. Most recent is another report from Germany of the effects of felt foam on plantar pressures [38]. These authors demonstrated reduced plantar loading at the side of the ulcer area and the cast. The cast gives support up to ankle level and may be removed at night. Walking is permissible with a walking sandal. Such casts have been successfully used in several centers.

Conclusion

In summary, abnormalities of pressure are key contributory factors in the pathogenesis of diabetic neuropathic foot ulceration in many cases. Early identification and preventive education of high-risk patients is indicated together with further investigations to identify specific high-risk areas. These might vary from the very simple assessment of pressure using a disposable mat to more complex measures of loading or subcutaneous tissue depth under the foot. Similarly, strategies to reduce foot pressures range from the simple, such as appropriate footwear, to the more invasive, which might include in the future injection of liquid silicone or other substances to increase padding under high-pressure areas. For those with foot ulceration, offloading is pivotal in the therapeutic strategy. Successful healing should follow if (1) pressure is relieved from neuropathic foot ulcers, (2) the arterial inflow is adequate, and (3) any infection is treated by debridement of infected tissue and appropriate antibiotic therapy. Whereas this article has focused on the first of these 3 strategies, detailed texts are available and cited for other aspects of diabetic foot management.

References

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