

Making prevention pay

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Article points

1. This article looks at the relative merits of the use of prescription insoles, in relation to their role in preventing ulceration.
2. The identification of risk factors alone does not prevent problems with the foot. It is the action taken following the screening process and what treatment or preventative measures are implemented that makes the crucial difference.
3. Providing clinically proven insoles will not only reduce the clinical risk, but also focus the patients' mind in self-management in relation to their risk of developing a potentially devastating episode of foot ulceration.

Key words

- Assessment
- Diabetic foot ulceration
- Insoles

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Individuals with diabetes have a 15–25% lifetime risk of foot ulceration (Singh et al, 2005), which can lead to considerable morbidity (Nabuurs-Franssen et al, 2005), limb loss (Fosse et al, 2009) and mortality (Boyko et al, 1996; Robbins et al, 2008). Hospitalisation of a patient with diabetes is more likely to occur as a consequence of foot disease than any other complication (O'Loughlin et al, 2010) and the resulting healthcare expenditure may represent up to 20% total diabetes expenditure in Europe and North America (Boulton et al, 2005; Lopez-de-Andres et al, 2010). With that in mind, this article examines the merits of the use of custom-made orthoses, in relation to their role in preventing ulceration or subsequent relapse. Evidence underpinning their performance is analysed, as are the potential benefits in terms of both patient and healthcare budgets.

With estimates of diabetes incidence predicted to see the greatest increases in the developing world (Unwin et al, 2010), diabetic foot ulceration is recognised as a global issue of major economic importance. Today, 3.8 million people across the UK are living with diabetes (Diabetes UK, 2014). Whether people are living with type 1 or type 2 diabetes, the condition causes serious complications leading to disability and early death. Diabetes costs the NHS an estimated £10 billion every year, equal to 10% of its budget. If action is not taken now, the longer-term costs and consequences associated with diabetes will be severe — for individuals, the NHS, and wider society. Good care saves money in the long run (Diabetes UK, 2014).

The cost of diabetic foot ulcers and amputations to the NHS in England in 2010/11 was estimated at around £662 million, with approximately £1 in every £150 the NHS spent being used on diabetic foot ulceration and amputation (NHS Diabetes, 2012). In 2010/11, 8.8% of all hospital admissions (with at least one overnight stay) for patients with diabetes involved a foot problem (NHS Diabetes, 2012).

The estimated cost of treating a single episode of diabetic foot ulceration is thought to be £5,200 on average (Ramsey et al, 1999). The financial impact of diabetes in Scotland is more than £1 billion with elemental cost breakdown pro rata to England. Throughout the UK, the most recent estimation is that the cost of ulceration and amputation alone in patients with type 1 and type 2 diabetes has risen above the £1 billion mark (Hex et al, 2012).

What is it that is putting patients with diabetes at risk of foot ulceration?

Peripheral vascular disease, a common finding in individuals with diabetes (Edmonds et al, 2006) together with peripheral neuropathy are the major risk factors for development of pedal ulceration (Khanolkar et al, 2008). Reduced vascular supply to an affected foot significantly delays healing, and is often associated with poor outcome.

Transcutaneous measurements of tissue oxygenation have been shown to correlate with vascular disease severity in ischaemic foot ulcers that occur in patients with diabetes (Graziani et al, 2007), with successful wound healing associated with higher TcPO₂ values (Poredos et al, 2005).

Numerous mainly passive strategies (targets for glycaemic control, blood pressure and lipids, smoking cessation, complication screening, specialist podiatry, patient education, and pressure relief) have been adopted with the aim of preventing foot ulcers in people with diabetes and neuropathy, vascular insufficiency or both (Dorresteijn et al, 2010; Lavery et al, 2010).

Are these measures being followed in the UK?

As part of Diabetes UK's *Putting Feet First* campaign, the traffic light risk stratification tool, which was developed by the Scottish Diabetes Foot Action Group, has now been adopted. This highlights the fact that all patients with diabetes should undergo foot screening annually to assess their risk of developing a foot ulcer that could lead to amputation. It is not only encouraged that the patient knows and understands their risk score, but the healthcare professional carrying out the screening should introduce appropriate preventative treatment and management plans to try and prevent problems developing.

But do clinicians really do this?

If a patient is screened and found to be at moderate risk (and are, therefore, at a six-fold increase risk of subsequent foot ulceration; Leese et al, 2006), the recommendation according to the traffic light system states the need for:

- Annual or 3–6 monthly assessment, according to need by a podiatrist or member of a foot protection team.
- An agreed and tailored management/treatment plan by podiatrist or the foot protection team according to patient needs.
- Written and verbal education with emergency contact numbers.
- Referral for specialist intervention if/when required.

If the patient is at high risk of developing a foot ulcer (an 83-fold increased risk of subsequent foot ulceration; Leese et al, 2006), the recommendation according to the traffic light system states the need for:

- Annual or 1–3 monthly assessment according to need by a specialist podiatrist or member of a foot protection team.
- Agreed and tailored management/treatment plan

by a specialist podiatrist or the foot protection team according to patient needs.

- Written and verbal education with emergency contact numbers.
- Referral for specialist intervention if/when required.

The traffic light system and its recommendations are not flawed, but as a screening tool could be interpreted as reactive not proactive. Do clinicians in practice actually introduce an 'agreed and tailored management/treatment plan according to patient needs', for 'at risk' patients or are patients just seen more often rather than being supplied with clinically proven preventative interventions to reduce the chance of ulceration?

According to various published research and national guidelines (NICE, 2004 and SIGN, 2010), insoles should be provided as a preventative measure as part of the 'agreed and tailored management/treatment plan according to patient needs', so are clinicians acting too late and just 'fire fighting' when a patient ulcerates, rather than implementing preventative measures?

Once a patient with diabetes has developed a foot ulcer, their chance of subsequent ulceration is 35–40% over 3 years, increasing to 70% over 5 years (Apelqvist et al, 1993). In a pertinent quote regarding reulceration, Professor David Armstrong said: "We do not heal patients' foot ulcers; we merely put them into remission." This is quite telling, meaning that once a patient has ulcerated, they are at high risk of another episode and so preventing the initial onset is key to avoiding subsequent episodes.

Guidance

SIGN (2010) guidelines on the management of diabetes state: "Custom-built footwear or orthotic insoles should be used to reduce callus severity and ulcer recurrence." The use of custom-made foot orthoses and prescription footwear reduces the plantar callus thickness and incidence of ulcer relapse (Colagiuri et al, 1995; Dargis et al, 1999; Uccioli et al, 1995). Patients who routinely wear their prescription shoes and orthoses are less likely to have ulcer relapse (Breuer et al, 1994).

NICE (2004) guidelines advocate the use of specialist footwear, insoles and orthotics: "Care of people at high risk of foot ulcers (neuropathy or absent

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Boulton AJ, Vileikyte L, Ragnarson-Tennvall G et al (2005) The global burden of diabetic foot disease. *Lancet* **366**: 1719–24

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Hinder S, Greenhalgh T (2012) "This does my head in". Ethnographic study of self-management by people with diabetes. *BMC Health Serv Res* **12**: 83

pulses plus deformity or skin changes or previous ulcer.)” Frequent review (1–3 monthly) should be undertaken by the foot protection team. At each review, the appropriate provision of intensified foot care education and specialist footwear and insoles should be evaluated and ensured. Meanwhile, NICE CG119 states that the healthcare professional should “perform an orthotic assessment and treat to prevent recurrent disease of the foot” (NICE, 2011a).

The upcoming revised NICE guidelines on the diabetic foot (expected in July 2015) will contain more about footwear, because insoles are now available on prescription and there is some newer published research that will undoubtedly be included.

The need to document risk of each individual with diabetes was incorporated in Quality and Outcomes Framework targets in April 2011. NICE Quality Standard 6 and SIGN’s Diabetic Foot Risk Stratification and Triage state that all people at increased risk should receive regular review by a member of a foot protection team (NICE, 2011b; SIGN, 2010). People with diabetes should be aware of their risk status and this entitlement. All people at increased risk should be referred promptly to a member of the foot protection team.

Several papers have been published addressing the difference in patient outcomes based on the application of various types of insoles. It should be noted that all such insoles referenced in these papers were of the static pressure offload type

For instance, various test results for static pressure offload (four groups — microcellular, polyurethane foam, moulded and leather board — showed that over 9 months, group 4 (no specific insoles) had over eight times as many ulcers than the other groups (Viswanathan et al, 2004).

Providing people with custom-made footwear to accommodate foot deformities and redistribute plantar pressures offers the opportunity to reduce the incidence of foot ulceration. The reulceration rate in people with previous diabetic foot ulceration is 40% (Pound et al, 2005), and the provision of specialist footwear is one of the tools in the diabetic foot clinic’s armamentarium to reduce this (Gooday et al, 2011).

Researchers in Sweden studied 114 patients with diabetes and a risk of developing foot ulcers over 2 years. The research proved that the long-term use of shoe orthoses significantly reduced diabetes-related amputations. Overall, only 0.9% of participants

developed new foot ulcers during the first year versus an industry average of 3% to 8% reported in similar diabetic populations. “By effectively distributing pressure under the sole, the inserts minimize the risk of ulcers and ultimately work to prevent amputations,” the researchers explained (Tang et al, 2013).

But what are foot protection teams actually doing for at risk patients?

NICE CG10 guidelines indicate that standard practice across the UK dictates that the higher risk a patient is of developing a foot ulcer, the shorter the durations should be between their visits and the more experienced the podiatrist should be, according to TRIEPodD-UK (2012).

The identification of risk factors alone does not prevent future problems. Foot screening does not prevent amputations, retinal screening does not prevent people going blind and breast screening does not prevent people dying of breast cancer. It is the action taken following the screening process and what treatment or preventative measures are implemented that makes the crucial difference.

Both NICE and SIGN recommend the use of preventative measures for patients at risk, such as footwear and insoles, but is this advice being followed? Is this because the provision of footwear and orthotics is looked upon as being unnecessary or too expensive, or is it due to the lack of NHS approved devices?

This scenario could now change, as the first orthotics have been accepted on NHS prescription (FP10/GP10) for all at-risk people with diabetes according to the traffic light system.

The acceptance of these insoles is a major step forward in the battle against foot ulceration and followed research carried out by the multidisciplinary diabetes foot team in Hairmyres Hospital, NHS Lanarkshire (Miller et al, 2011). As Professor Armstrong stated after hearing the news that the UK had approved insoles for at risk patients with diabetes on prescription: “This is absolutely, positively huge. We now can begin working to do what we say we have already been doing; making prevention pay.”

In Miller et al’s study (2011), it was found that when Liqua Care® therapeutic insoles were worn by individuals with diabetes and vascular insufficiency, peak forefoot pressures were reduced by 21.5%. Additionally, following 2 weeks’ insole use, the researchers observed a 5% improvement in

Khanolkar MP, Bain SC, Stephens JW (2008) The diabetic foot. *QJM* **101**: 685–95

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transcutaneous tissue oxygen tension when measured at the great toe under controlled conditions.

Together these results suggest that Liqua Care insoles would be an effective intervention for people at risk of foot ulceration. A particular advantage of these insoles is they can be inserted into most patients' own footwear, which require no modification. This results in better concordance because patients find it more acceptable to wear their own footwear rather than prescription footwear. The authors' conclusion states unequivocally: "these results suggest that Liqua Care insoles would be an effective intervention for subjects at risk of foot ulceration." The pressure offloading capability is exceptional and the increase in patient circulation is unique, hence the device is without precedent.

Consideration of footwear suitability should always be at the forefront of the healthcare professional's thoughts, especially when the use of foot orthoses results in the potential to enhance risk through lack of compatibility between the device and the shoe. Due to the thin profile of the Liqua Care insole, risk in fitting to appropriate footwear is reduced. It is important for the patient and foot care staff to conform to the accepted sizing dimensions for footwear suitability, and if this is adhered to, the use of footwear that may seem more cosmetically acceptable and, therefore, ensure enhanced concordance can be utilised.

Given the results and reduction in peak pressure, and providing there is not significant deformity, the use of well-fitting, supportive high street shoes with shock attenuating outer soles, combined with Liqua Care insoles means that offloading can take place prophylactically with minimum impact on shoe fitting.

Diabetes is the exemplar of long-term conditions and recent research has shown that a person with diabetes spends only around 1% of their time in the company of healthcare professionals. The remaining 99% of the time, the individual is managing their own condition (Hinder and Greenhalgh, 2012). The ability to self-manage their own condition requires the person to be fully empowered and resourced to do so (i.e. supported and educated, and with the ability to take control of their condition and their lifestyle). Providing clinically proven insoles to help in this process will not only reduce the clinical risk, but also focus the patients' mind in relation to their risk of developing a potentially devastating episode of foot ulceration.

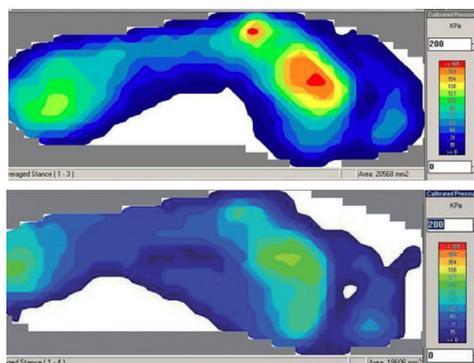


Figure 1. Pressure mapping showing the effectiveness of the Liqua Care[®] insoles. The image above shows the foot in a 'regular' shoe, while the image below shows the foot with Liqua Care insoles.

Conclusion

This is a major step forward in the battle against foot ulceration and demonstrates a sea change in the national approach. Given that diabetes foot ulceration and subsequent amputation is costing the NHS £1 billion per annum (Hex et al, 2012), if these insoles only prevented 1% of these patients ulcerating then it would save £10 million per annum, as well as have a significant effect on those patients' quality of life.

A 2-year follow up of the patients included in the Liqua Care trial revealed no reported cases of ulceration/reulceration. It is not unreasonable, therefore, to assume that this clinically proven prophylactic intervention could easily prevent 5% of ulceration/reulceration, so a saving of £50 million could easily be achieved through a small investment.

Earlier preventative interventions and making prevention pay make perfect sense, meeting the stated and widely published aims of NHS Diabetes, NICE and Diabetes UK, and mirrors the views of Scandinavian countries, such as Norway and Sweden, which have adopted the preventative approach using insoles with good effect.

The means are available to risk stratify and there is now potentially a clinically proven method of preventing foot ulceration on prescription. There are exciting times ahead – not only for clinicians treating patients with diabetes, but also for patients who have not been offered such hope consistently or early enough in their disease process. ■

Declaration of interest

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More information regarding Liqua Care insoles and the research can be obtained at www.liqua-care.co.uk/clinical.asp

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