Achieving plantar pressure redistribution in people with diabetes: More than an offloading device

Ruth Thompson, Deirdre O’Sullivan-Drombolis, Janet L Kuhnke, Mariam Botros

Diabetic foot ulcers result in a significant cost to the healthcare system. Diabetes is a chronic systemic disorder that affects the entire body. Due to the medical complexity of patients with diabetic foot ulcers, a multidisciplinary approach to their treatment has been shown to reduce amputation and recurrence rates. This article focuses on the types of offloading devices, aids and exercises that can be utilized in order to successfully achieve pressure offloading and wound closure.

Diabetic foot ulcers represent significant medical and financial burdens to the healthcare system. In addition there can be high personal costs to patients including changes to work, employment, and quality of life (Ribu, 2008; Waters and Holoway, 2009) It is estimated that 15-20% of people with diabetes will develop a foot ulceration during their lifetime (Singh et al, 2005). Furthermore, foot complications account for longer hospital stays than any other complication of diabetes. (Reiber, 2001; International Working Group on the Diabetic Foot, 2003) Diabetes is the most common cause of non-traumatic lower extremity amputation; this occurs in roughly 20% of diabetic foot ulcer cases. (Dang, 2003) The diabetic comorbidities including sensory neuropathy, motor neuropathy and peripheral vascular disease contribute to the development of diabetic foot ulcers.

The most common causal pathway for the development of a diabetic foot ulcer is repetitive microtrauma, often due to ill-fitting footwear, or foreign objects in shoes. This kind of repetitive microtrauma is able to continue in persons with diabetes due to the presence of sensory neuropathy, or loss of protective sensation (LOPS; Pecoraro, 1990) In a foot with normal sensation, offloading is much easier to obtain as the patient is able to feel pain, and therefore is able to identify and communicate when an area needs pressure offloading. Someone with LOPS is less able to perceive even the slightest trauma to their feet and is therefore less able to perceive if the pressure or shearing force has been reduced or increased over the affected area. The development of motor neuropathy causes changes in the musculature and shape of the foot. Motor neuropathy is also responsible for increases in peak plantar pressures (PPP) and changes in the way a person walks. These conditions can magnify the effects of repetitive microtrauma. The development of peripheral vascular disease can lead to inadequate circulation to support healing. Furthermore high blood glucose levels can lead to a muted immune response leading to ineffective infection control.

The time it takes to achieve wound closure for a diabetic foot ulcer can be very long. (Wu, 2005) Even with appropriate management, wound closure rates can range widely. Large multicenter trials showed rates of wound closure to be 24% at 12 weeks and 31% at 20 weeks. (Jeffcoate, 2003; Margolis, 1999) One of the primary reasons that these times are so long may be that patients, caregivers and health care providers often ignore or don’t understand the "A combination of foot deformity, loss of protective sensation and inadequate offloading leads to tissue damage and ulceration."
importance of using plantar pressure redistribution devices to promote wound healing. Plantar ulcerations require aggressive and effective offloading in order to achieve and maintain wound healing. The ongoing repetitive microtrauma applied to the area of ulceration causes continual damage to the wound and needs to be reduced in order to promote healing.

**Offloading strategies and devices**

There are a number of different offloading strategies and devices that can be used for reducing PPP. A successful management plan will often need to incorporate more than one strategy and device based on wound presentation, access to devices and patient adherence to the treatment plan. Many of these strategies and related devices can significantly alter gait and put already unsteady patients at high risk of falling. The treatment plan related to offloading should include a gait assessment and fitting with a gait aid to prevent falls.

**Non-weight bearing**

The absolute best way of offloading PPP is to be 100% non-weight bearing maximizing the combined use of bed rest, wheelchairs, walkers or crutches. These methods are very challenging to use on a daily basis and are difficult to adhere to from a patient, family, and caregiver perspective. Non-adherence to treatment plans is a significant barrier to achieving treatment efficacy. (Bus, 2012) Bed rest as an offloading strategy is unrealistic, and is rarely utilized. There are also significant negative side-effects associated with being 100% non-weight bearing during bed rest including muscle wasting, deconditioning, and decreases in bone density. Additionally, complete bed rest can have significant impacts on mood as well as mental and emotional wellbeing.

The use of wheelchairs, walkers, and crutches requires skill and patients need to be taught how to use them properly. Patients should also be fitted properly for these devices by a knowledgeable clinician. If use of this strategy and related devices is the treatment of choice it is important to ensure that the patient is followed by a multidisciplinary team including a physiotherapist and/or an occupational therapist to minimize negative effects by incorporating an exercise program and ensuring proper fitting and use.

Cardiovascular exercise is important for overall wellbeing and glycemic control. Exercises such as arm ergometry, and recumbent biking can aid with cardiovascular health without increasing pressure through the feet. Exercises carried out while in bed or in chair seated position can be taught using resistance bands or water bottles, to aid muscle strengthening. Patients should be encouraged to move as much as possible in their bed or chair, carrying out exercises (e.g. armchair push-ups) every 2 hours.

**Total contact casting**

Many studies cite the total contact cast (TCC) as being the ‘gold standard’ for offloading of a plantar neuropathic ulceration. The TCC uses a custom molded, minimally padded cast that maintains contact with the entire plantar aspect of the foot and the lower leg. This method of casting is very effective in treating a majority of non infected, non-ischemic plantar diabetic foot wounds, with healing rates ranging from 72% to 100% over a course of 5–7 weeks (Mueller, 1989; Armstrong, 2001; Caravaggi, 2000). These are custom-made, irremovable casts constructed primarily of either fiberglass and/or plaster. The TCC works by distributing pressure over the entire plantar surface of the foot thereby decreasing the PPP and shear in any one location. Due to the patients’ LOPS, the risk of ulcerations on other parts of the leg is
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high and these casts must be applied by skilled technicians and/or clinicians to minimize the percentage of iatrogenic lesions.

Despite the fact that the TCC is considered to be the best method for offloading pressure and increasing healing rates it is rarely used in practice. This is thought to be due to funding considerations, limited knowledge of their use, and lack of access to skilled interdisciplinary teams experienced with the use and application of these devices.

Removable cast walkers and instant TCCs

Removable cast walkers (RCW) can be very useful in the treatment of diabetic foot ulcers of the forefoot. Studies have shown that similar to the TCC, they can reduce plantar forefoot pressures (Armstrong, 2002). One of the major advantages of RCWs over TCCs is that they can be removed for dressing changes and for wound, foot and leg inspection; this is also one of the major disadvantages of RCWs. Studies have shown that patients wear them for about 30% of the time that they report wearing them (Armstrong, 2003). More recently, clinicians have been making RCWs irremovable by adding a layer of plaster, fiberglass or tying cable ties around the casts (Armstrong, 2003). These are called instant TCCs (iTCCs). The iTCCs have shown similar successes to TCCs.

The iTCCs primary advantage over the TCC is that the devices are available over the counter and do not require a skilled technician for application. However, the clinician must still be knowledgeable in the proper selection and sizing of the RCW for optimal pressure redistribution. The upfront cost expenditure is decreased with the iTTC as it can be reapplied after each dressing change. In the case of the TCC a new device needs to be fabricated with each cast change and this typically occurs on a weekly basis. An advantage of the TCC over the iTCC and RCW is that the TCC is custom made and with skilled application can be tailored to the patient's wound and lifestyle. It is important to ensure that the patient protects the contralateral limb when using any of these devices.

Charcot restraint orthotic walker

The Charcot restraint orthotic walker (CROW) is a custom made bivalved ankle foot orthosis. It is generally used during both the healing process and the quiescent stages of the Charcot neuroarthropathy process where joint stability must be maintained. The CROW can also be used for offloading wounds in the Charcot foot. It is removable and so allows for skin and wound inspection. CROWs are custom made orthotic devices and should be prescribed, manufactured and dispensed by knowledgeable clinicians.

MABAL shoe and scotch cast boot

The MABAL shoe was first introduced into the literature in 2000 by Hissinki and Manning. It is a removable combination of a fiberglass cast shoe to provide an alternative to total contact casting for the treatment of diabetic neuropathic ulcers. It acts as a cross between a healing sandal and an RCW (Hissink et al, 2000). Scotch cast boots (Leicester boot) are also a combination of a removable cast and a shoe. They are custom made to the foot and can be manufactured in a way that offloads the plantar heel – something that is difficult to do with most commercially available devices. Since both devices are removable patient adherence to their use can be low (Burden et al, 1983; Jones et al, 1989; van Schie, et al, 2003).

Felt

Felt padding applied directly to the foot can be an inexpensive pressure-reducing strategy. The felt is applied directly to the foot often with openings or apertures placed proximal to the wound. The padding remains in place on the foot throughout the healing process providing a built in amount of offloading even when the offloading sandal or shoe is not being worn. Bathing may become an issue, as the felt must not get wet, so effective covering of the padding during bathing is essential. Also the padding can compress over time making frequent reapplication necessary. Caution must be taken to ensure that there is adequate depth in the footwear if this option is to be used. Skin integrity must be closely monitored as the adhesives can cause skin tears when the padding is removed.

Healing sandals

Healing sandals can be useful as an intermediary step in offloading (Giacalone et al, 1997). They tend to be lightweight with a rigid sole and are available in 4–5 sizes. They are relatively inexpensive high and these casts must be applied by skilled technicians and/or clinicians to minimize the percentage of iatrogenic lesions.

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“Pressure redistribution devices should always be part of the treatment plan for an ulcer.”

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to purchase though may need to be replaced throughout the treatment of the wound. Healing sandals often have a removable lining that can be easily modified to increase the amount of offloading in a specific area. They do not control foot motion well, and can lead to increased stress on other areas of the foot if their use is not well monitored. Healing sandals are generally available in three different configurations: flat, negative heel and negative forefoot.

Surgical offloading
Corrective or reconstructive foot surgery is an important treatment in the management of patients with diabetic foot ulcers. Several prophylactic and curative procedures have been found to have an effective role in the short term prevention or management of a wound. Flexor and extensor tenotomies, Achilles lengthening procedures and silicon injections under the metatarsal heads may only temporarily reduce plantar forefoot pressure and should be used in conjunction with both footwear and orthoses as required. The challenge still remains in patient adherence to protective footwear and offloading devices.

Footwear and custom foot orthoses
Regular footwear and custom foot orthoses alone do not provide enough pressure offloading to support wound closure. Their careful selection and use are vital to keeping skin intact once wound closure has been achieved, but should not be relied upon to offload an ulcer.

Recurrence
Once an ulceration has been sufficiently offloaded in order to support wound closure, we know that patient education and assessment must continue. Recurrence rates of wounds are alarmingly high; ranges of between 30%–70% per year have been found even in specialty clinics. The reasons for these high recurrence rates are multifaceted but one way to reduce these rates has been to educate and to actively involve patients and their families in self care. Diligent monitoring of patients’ feet and having the ability to access ongoing care and offloading in a timely manner may reduce these high rates of recurrence. Patients need to be properly transitioned from their wound healing offloading device to appropriate footwear and custom foot orthoses or other orthotic device that will also redistribute pressure. These shoes and custom foot orthoses can be expensive and access to a qualified clinician and/or team can be challenging. Proper foot care by qualified regulated health care providers is an important aspect of prevention of recurrence. Patients that have had even a single ulceration need to be carefully and continually monitored and reassessed.

Patient and family education
Diabetes care, prevention of foot ulcers, and care of complications must be organized around the patient, family and caregivers. There are many factors that may influence health behaviors and adherence to care options. Clinicians must initiate and sustain clinical quality improvement strategies to remind patients that utilizing their offloading devices is essential for wound closure. Without the sensory ability to recognize potential trauma and friction of their feet from inappropriate footwear, many patients will continue to use the footwear that was the initial cause of the problem. Clinicians can create patient reminders and supports to encourage patients to properly use their shoes, devices or adaptive footwear in the same ways they empower patients to conduct glucose monitoring and foot exams.

The importance of wearing the offloading device cannot be over stated. What often occurs is that the patient will wear their device(s) while they are outside of the home but remove them when they get home impacting both wound closure and re-ulceration rates. This behaviour negates much of the benefit that was obtained from having worn the device outside of the home. Not only will the patient remove the device, but many patients report that they will wear only socks and even go barefoot around the house, or wear an older, softer, less appropriate slipper or shoe. It is important to educate both the patient and their family about the consequences of this behaviour. Not wearing offloading devices when at home is likely one of the primary reasons that patients using removable devices tend to have much longer wound healing rates than those using non removable devices.
Disturbances are often rooted in the musculature further up the kinetic chain. In general, stretches for the calves, hamstrings, hip flexors, and hip external rotators as well as strengthening for the foot intrinsics, dorsiflexors of the foot, inner quadriceps, and gluteals are most important but every patient should be assessed to determine their individual imbalances. Based on an individual gait assessment a patient can be fitted to use the most appropriate gait aid if necessary. The use of a gait aid such as a cane can reduce the pressure through the contralateral limb by up to 21.5% as well as provide sensory feedback (Wertsch, 1990). Other gait aids such as walkers, and crutches further decrease the load by 40%–60% and up to 100% if used with a non-weight bearing gait (Wertsch, 1990). Generally walkers provide more support than canes and crutches, therefore, patients who are more unsteady are usually more suited to use a walker.

Physical therapy techniques may be able to correct the mobile deformities including joint mobilizations. An individual assessment is necessary to identify the joints which are limited but persons with neuropathy tend to have limitations moving the ankle joint into dorsiflexion and also at the great toe into extension. There are several hands on techniques which can be used to increase this movement in order to normalize range of motion and gait. In the patient that experiences neuropathic pain there are several modalities including transcutaneous nerve stimulation and acupuncture that can be effective treatment options to reduce symptoms (Deworkin, 2003). Working with a physical therapist may not only assist in reducing PPP but also aid in maintaining the patient’s independence. Well-structured exercise programs can be empowering to patients and have a positive effect on their overall health.

**Conclusion**

Successful plantar pressure redistribution in order to achieve wound healing is heavily dependent on selecting the most appropriate offloading device. It requires a specialized and integrated approach that addresses all factors relating to pressure with a strong patient focus. Patient and clinician goals should be focused around achieving sufficient pressure relief to enable wound closure, prevent wounds on other parts of the foot and avert reoccurrence.

**Utilizing technology**

Technology can be used in the clinical setting in order to educate and provide information regarding the development and complications of foot ulcerations. These technologies can range from simple charts and images to more complex in-shoe pressure measurement systems. Routinely measuring skin temperatures with a dermal thermometer is showing potential as an effective tool for the prevention of ulcers. Digital photographs provide a good and easy way of tracking progress for both the patient and the health care provider. They provide a visual record of progress and can be both reassuring and motivating for patients.

In-shoe pressure measurement systems provide a concrete visual demonstration of the direct pressure over the ulcerated area. Using these systems, health care providers may help to emphasize the importance of the offloading device by showing the patient, caregivers and other members of the clinical team a computerized visual output of the pressure relief that has been obtained with the offloading device.

**Role of physical therapy in treatment and prevention**

Foot deformities can be either fixed (the shape of the bones have become altered and no longer move), mobile (the deformities are as a result of muscle imbalances), or a combination of fixed and mobile. Fixed foot deformities need to be accommodated for through the use of extra depth footwear and orthoses. Mobile deformities may be altered through stretching, exercise and manipulations. Patients with diabetic neuropathy should be referred to a physical therapist. The physiotherapist can assist with the development of an exercise regime including stretches and strengthening to help combat the mobile foot deformities that may have developed as a result of neuropathy (Dallemole, 2012). A gait assessment and training with or without a gait aid can also help to decrease pressures on the foot and wounded area (Mueller, 1994).

A safe conditioning program to aid in glycemic control without increasing pressure to the foot can be developed. Exercises which focus on balancing the musculature around the ankle, knee, and hip are important in correcting the mobile foot deformities and gait difficulties. It is important not to focus just on the foot area as the deformities and gait disturbances are often rooted in the musculature further up the kinetic chain. In general, stretches for the calves, hamstrings, hip flexors, and hip external rotators as well as strengthening for the foot intrinsics, dorsiflexors of the foot, inner quadriceps, and gluteals are most important but every patient should be assessed to determine their individual imbalances. Based on an individual gait assessment a patient can be fitted to use the most appropriate gait aid if necessary. The use of a gait aid such as a cane can reduce the pressure through the contralateral limb by up to 21.5% as well as provide sensory feedback (Wertsch, 1990). Other gait aids such as walkers, and crutches further decrease the load by 40%–60% and up to 100% if used with a non-weight bearing gait (Wertsch, 1990). Generally walkers provide more support than canes and crutches, therefore, patients who are more unsteady are usually more suited to use a walker.

Physical therapy techniques may be able to correct the mobile deformities including joint mobilizations. An individual assessment is necessary to identify the joints which are limited but persons with neuropathy tend to have limitations moving the ankle joint into dorsiflexion and also at the great toe into extension. There are several hands on techniques which can be used to increase this movement in order to normalize range of motion and gait. In the patient that experiences neuropathic pain there are several modalities including transcutaneous nerve stimulation and acupuncture that can be effective treatment options to reduce symptoms (Deworkin, 2003). Working with a physical therapist may not only assist in reducing PPP but also aid in maintaining the patient’s independence. Well-structured exercise programs can be empowering to patients and have a positive effect on their overall health.

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The effectiveness of pressure redistribution in the diabetic foot needs to encompass a holistic approach that takes into account patient characteristics, environmental factors, the device, activity and gait modification, patient adherence, access to treatment options and funding.

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