



MANAGEMENT OF DIABETIC FOOT

ICRC IMPLEMENTATION PLAN

COVERING PATIENT EDUCATION, FOOT EXAMINATION WITH RISK STRATIFICATION, FOOTWEAR, INSOLES AND OFFLOADING TO PREVENT AND HEAL DIABETIC FOOT ULCERATIONS

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ACRONYMS

ABI	Ankle brachial index
AFO	Ankle-foot orthosis
CROW	Charcot restraint orthotic walker
DFU	Diabetic foot ulceration
EVA	Ethyl vinyl acetate
IWGDF	International Working Group for the Diabetic Foot
MPJ	Metatarsal phalangeal joint
NICE	National Institute for Health and Care Excellence
PHC	Primary health-care clinic
PRC	Physical rehabilitation centre
PRP	Physical Rehabilitation Programme
SGED-SSED	Schweizerische Gesellschaft für Endokrinologie und Diabetologie/Société Suisse d'Endocrinologie et Diabétologie [Swiss Society of Endocrinology and Diabetology]
TCC	Total-contact casting

PURPOSE

This implementation plan is intended to guide orthotists at centres assisted by the ICRC Physical Rehabilitation Programme (PRP) in:

- the provision of footwear and insoles to help prevent diabetic foot ulcerations (DFUs)
- the provision of offloading devices to help heal DFUs.

It also provides guidance to other staff caring for people with diabetes as to when to refer a patient to a physical rehabilitation centre.

The plan is evidence-based and consistent with the International Working Group for the Diabetic Foot (IWGDF) guidance on footwear and offloading and with Guideline 19 of the National Institute for Clinical and Health Excellence (NICE).¹

It was drawn up by the PRP Diabetes Working Group and has been reviewed by external experts. The aim is to help physical rehabilitation centre (PRC) staff develop a clinical pathway as easily as possible.

The document consists of three sections:

1. Foot assessment.
2. Stratification.
3. Footwear, insoles and offloading.

Referrers such as primary health-care clinics (PHCs) or hospitals will be most interested in the first two sections, while orthotists and PRC staff will need to use all three.

1 *Diabetic foot problems: prevention and management*, Recommendations: <https://www.nice.org.uk/guidance/ng19/chapter/Recommendations>, accessed 10 March 2020.

INTRODUCTION

The number of people in the world with diabetes (age-standardized) has doubled since 1980; in 2016, an estimated 422 million people were living with diabetes. Its prevalence is growing most rapidly in low- and middle-income countries (1). Worldwide, about 6% of diabetes patients are suffering from foot problems (2). Peripheral arteriopathy is an increasingly common comorbidity and compromises the healing process of foot ulcers. Preventing and managing arteriopathy is therefore essential.

Diabetic foot ulceration and Charcot foot have been shown to reduce life expectancy (3) and to increase the risk of lower limb amputation, by a factor of 36 (4,5). Up to 85% of lower limb amputations in people with diabetes follow a DFU (5,6). People with neuropathy in the lower limb often lack protective sensation and suffer from impairments to the motor and autonomic nervous systems that lead to reduced physical stress tolerance in the sole of the foot (7).

A loss of protective sensation can lead to insensate areas with higher pressure not being automatically unloaded. Normally, people adjust posture to relieve discomfort or pain, but the absence of pain can result in high pressures occurring for longer periods, which can lead to ulcerations and reduced blood flow and may eventually cause cell death, skin breakdown and the development of an open wound (8).

For a plantar DFU to heal, it requires a mechanical environment that will not disrupt the healing tissue; this is a “mechanical problem more than a medical problem” (5). To achieve that, mechanical stress must be removed from the wound and the immediately surrounding tissue (9).

Offloading and pressure redistribution by appropriately trained professionals is an important part of care for people with DFUs and for those at increased risk. Pressure redistribution to heal a DFU and prevent its occurrence can reduce the risk of amputation by reducing the mechanical disturbance to tissues (10). Therapeutic shoes and insoles have been shown to bring about a 2- to 4-fold reduction in re-ulceration compared with standard shoes (11).

INTERDISCIPLINARY CARE

In isolation, offloading to help heal an ulcer, and preventive measures such as orthotic insoles and footwear, are not sufficient to achieve good outcomes. The full resources of a physician-led multidisciplinary team are necessary to adequately care for any patient experiencing a diabetic foot ulceration or at risk of experiencing one (12).

While the orthotist and physiotherapist may be delegated responsibility for mechanical control of a foot and can play a role in education and lifestyle change, the treating physician remains responsible for overall care, with the role of coordinator in such areas as vascular sufficiency, together with wound, microbiological and metabolic control of an individual with diabetes. A good outcome requires a comprehensive multidisciplinary approach led by this physician, in line with the continuum of care (13).

Complications of diabetic foot can be prevented through:

1. Patient education, promoting lifestyle changes and adequate self-care.
2. Regular foot examination with risk stratification (see below), to evaluate the level of risk.
3. The provision of appropriate footwear and, if possible, light-coloured socks so the patient can see any blood or exudation when undressing at night.
4. Optimization of glycaemic control, at a PHC, because for each 1% of HbA_{1c} increase the risk of arteriopathy rises by 25–30% (14).

The ICRC uses the continuum of care to understand the health system as it relates to people affected by conflict. A linear model does not work well when it comes to non-communicable diseases such as diabetes. How the different parts of the health system fit together is better demonstrated by Figure 1.

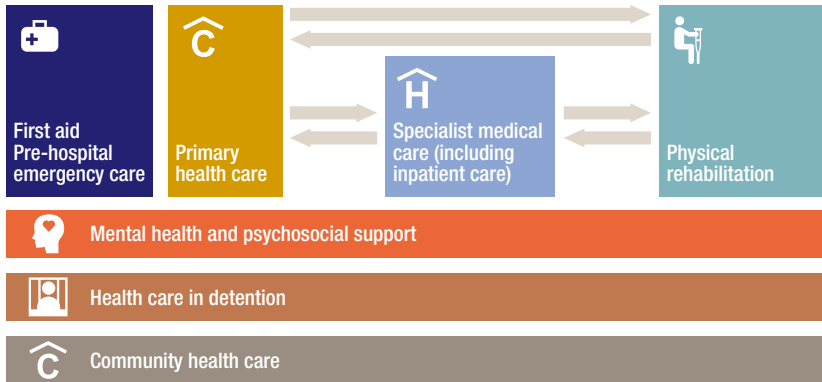


Figure 1: Continuum of care – nonlinear referral pathway for people with diabetes

Referral pathways need to be formally negotiated in each context and must take account of existing structures, relationships between centres and norms. Tightening the linkages is important; when a patient is referred from one part of the system to another, the first part of the system may no longer be following up, but we do not know whether the next part of the system has started to engage with the patient. Good coordination between centres and individuals is essential, to ensure that people are not lost at the point of referral.

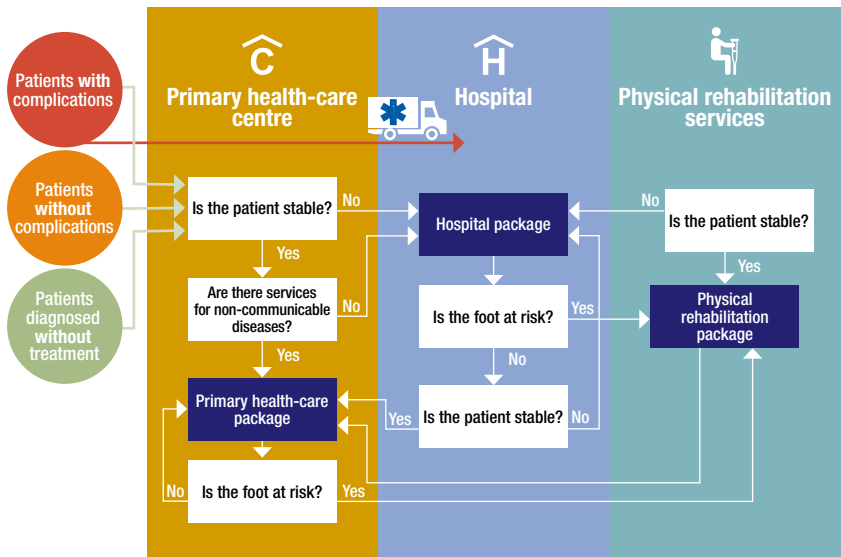


Figure 2: Referral pathway for people with diabetic foot

Commonalities between parts of the health system strengthen linkages. Referral is aided by clear and common assessment, a good understanding of the triggers for referral and awareness of those triggers on the part of both the referrer and the part of the health system receiving the referral. Common diagnostic tools, medicines, protocols and patient education should be encouraged as much as possible, to improve the overall response.

ONE: FOOT ASSESSMENT

Regular, standardized assessment of feet is important for people with diabetes. Too often, socks and shoes are not even removed during an appointment, to check the feet and test their sensitivity.

A documented, standard assessment makes it possible to detect changes over time.

FOOT EXAMINATION

1. Check for active disease: ulceration, resting pain, gangrene or cellulitis. If there is a wound, it is very important to find the cause.
2. Check foot temperature and colour:
 - a. Cold (thermal gradient), pale or dusky with hair loss,² changes in skin texture,³ low systolic blood pressure index; these symptoms may indicate ischaemia or low oxygenation.
 - b. Warm, red or swollen: may indicate infection or acute Charcot foot.
3. Check for lesions and deformities: calluses, deformed nails, foot deformities, toe deformities, fungal infection, macerated web spaces and skin fissures.

NB: An ulcer can form under a callus and the callused skin can add to the pressure!
4. Check the quality of footwear.
5. Screen for peripheral arterial disease (arteriopathy).
6. Screen for loss of protective sensation (neuropathy) (15).

-
- 2 The relevance of hairiness is that where there are hairs, TCPO₂ is good, whereas below the threshold of critical ischaemia, hairs are absent. In certain cases some hairs remain on the dorsal side of the hallux, but they no longer hold – one can pull them out with no pain, even in the absence of neuropathy.
 - 3 In the case of lower arterial insufficiency, the clinical examination involves placing the dorsal part of the examiner's hand on the patient's hip and sliding the hand towards the distal end of the lower limb. When it reaches the area where the critical ischaemia threshold is located, the skin texture becomes rougher and the hand slides less smoothly, it "stumbles". Above this area, TCPO₂ is > 40 mm Hg (so the chances of healing are good). Below, the probability of healing is significantly lower. TCPO₂ in the foot is not significant.

TESTING FOR NEUROPATHY USING A 10 G MONOFILAMENT

Testing for sensory neuropathy is an essential part of stratification.

- Ask the patient to sit or lie down with feet exposed.
- Explain the test on a non-neuropathic skin area (e.g. the forearm).
- Ask the patient to close their eyes and respond with a “Yes” when they feel contact of the 10 g monofilament with the foot.

Press the monofilament at 90 degrees to the skin (but not on areas with thick skin) until it buckles under the force.

Most common testing sites. Test with only the monofilament touching the foot (i.e. do not hold the foot with the other hand):



Figures 3-4: Monofilament testing: most common testing sites



Figures 5-8: Correct use of monofilament

Inability to feel at one site (tested three times) indicates the patient has lost protective sensation. Clean the monofilament after each use and allow a 24-hour recovery period after 100 compression cycles (16).

TESTING FOR NEUROPATHY USING A 128 HZ TUNING FORK

Another way of testing is to apply a tuning fork bilaterally over the tip of the great toe (17). Strike the tuning fork and then press it against the toe; if the patient cannot feel the vibration, they are at high risk (17).

SIGNS AND SYMPTOMS OF DIABETES-RELATED PERIPHERAL NEUROPATHY		
Type of neuropathy	Clinical signs	Clinical implications
Sensory neuropathy	Loss of sensation to light touch, pain and temperature.	Loss of pain significantly increases the risk of unnoticed injury or trauma, which can lead to tissue breakdown and foot ulceration.
Motor neuropathy	Poor nerve supply to the muscles in the leg and foot, which can cause foot deformity.	Foot deformities cause the foot to function abnormally. This can result in areas of high pressure on the foot and can lead to foot ulceration.
Autonomic neuropathy	Absence of sweating (anhidrosis) in the foot, which can cause dry skin.	Anhidrosis can lead to callus formation and skin fissures (cracks in the skin), which can increase the risk of infection and ulceration in the diabetic foot.

Table 1: Signs and symptoms of diabetes-related peripheral neuropathy
From McIntosh and Halford, 2014 (18).

SCREENING FOR PERIPHERAL ARTERY DISEASE

History: intermittent claudication and rest pain. The pain is not systematic, because of the sensory neuropathy.

Palpate posterior tibial and dorsalis pedis artery in both feet and record pulse as present or absent.

Ankle brachial index (ABI): measured using a Doppler device. Ratio of the highest systolic blood pressure at the ankle to the systolic blood pressure in the arm.

Interpretation of ABI as an indicator of severity of arterial disease: <0.9 is considered abnormal. Peripheral artery disease is excluded if ABI lies between 0.9 and 1.3 (IWGDF on peripheral arterial disease, 2015).

BUERGER TEST

In a limb with normal circulation, the toes and sole of the foot stay pink even when the limb is raised by 90 degrees. In an ischaemic leg, elevation to 15 degrees or 30 degrees for 30 to 60 seconds may cause pallor.

To perform this test, elevate both legs to an angle of 60° for 60 seconds.

The severity of the arteriopathy can be graduated between 0 and 4 as follows (19):

- 0 – Sole remains pink after 60 seconds.
- 1 – Sole becomes pale at 60 seconds.
- 2 – Sole becomes pale at between 30 and 60 seconds.
- 3 – Sole becomes pale in less than 30 seconds.
- 4 – Sole becomes pale in decubitus (lying down) position.

The time required for re-coloration in decubitus position depends on the level of obstruction.



Figure 9: Buerger test, with the pale sole indicating arteriopathy

ANKLE RANGE OF MOTION

People with diabetes often have a lack of dorsal flexion of the ankle. This reduced range of motion (less than 5° of dorsal flexion) increases forefoot plantar pressures, leading to an increased risk of plantar ulcers. In some cases, gastrocnemius recession or Achilles tendon lengthening may be required. If these measures are not possible, provide a rocker sole under the footwear or modify the heel of the shoe.

VENOUS FILLING TIME

In a supine position, a superficial vein of the foot emptied of blood by the examiner's finger normally fills up almost immediately as soon as the pressure on the vein is released. The longer the venous filling time, the more severe the arterial insufficiency.

TWO: STRATIFICATION

Information from the assessment is used to group patients together into strata, a process known as stratification. Stratification makes it easier to apply the treatments with the best evidence for each group of patients.

Risk stratification involves grouping patients into categories of similar characteristics so that they can receive standard treatment that is based on the best evidence. Stratification, or grouping, allows for simpler and consistent clinical decision making. The ICRC uses the IWGDF stratification tool in Table 2 below to group patients who have ulcers or are at risk of developing them.

If a patient presents with other complications of diabetes not included in this stratification, such as rest pain, gangrene, cellulitis, ischaemia, fever, drowsiness or abnormal breathing, or if they are visibly unwell, they should be referred to the closest health facility for medical care.

People diagnosed with diabetes should undergo regular foot checks for early signs of foot complications; this is an important part of preventing DFU. These checks should be conducted in primary health-care settings and in hospitals. The stratification system uses information from these foot checks to determine treatment and to provide appropriate patient-education material regarding prevention and care. PRP centres will also perform basic foot checks to enable stratification to be carried out. This in turn makes it possible to select the appropriate care pathway for the patient, depending on severity.

Anyone who has already undergone amputation secondary to diabetes is automatically in the high-risk category; it is important to take measures to protect their remaining limb.

In Table 2:

- the left-hand column lists the categories (Low, Moderate, High risk/in remission and Very high risk)
- the middle column defines each category in simple terms, to allow people to be categorized

- the right-hand column contains a simple action plan. The plan will need to be expanded for each individual, but this simple explanation indicates the service categories to which one should refer the patient, hence standardizing the care that people receive based on their clinical presentation.

The stratification system and foot check should be standardized within a health-care system as far as possible. If another system is commonly used in the local context, the characteristics of each category within the “traffic light” system can be adapted to indicate referral/treatment criteria. This type of stratification system has been shown to predict foot ulceration reliably, and so helps direct limited resources to people at greater overall risk (20).

Category	Characteristics	Actions and frequency
0 – Low risk	No peripheral neuropathy , no signs of peripheral arterial disease, no other risk factors	<ul style="list-style-type: none"> • Annual review by primary health care team, including foot check to detect any deterioration • Footwear advice • Written and oral education on self-management
1 – Medium risk	Peripheral neuropathy or arteriopathy (without callus or deformity), unable to self-care or on dialysis	<ul style="list-style-type: none"> • Review by primary health-care team at intervals of no more than six months, including foot check to detect any deterioration • Footwear/insole advice and review • Written and oral education on self-management, including emergency contact details
2 – High risk/in remission	Peripheral neuropathy with peripheral arterial disease and/or a foot deformity	<ul style="list-style-type: none"> • Primary health-care team review every three to six months • Specialist care review at intervals of no more than six months • Check of footwear and/or insoles • Written and oral education on self-management, including emergency contact details
3 – Very high risk	Peripheral neuropathy and a history of foot ulcer or lower extremity amputation , Charcot foot or kidney failure , active ulceration	<ul style="list-style-type: none"> • In case of active ulcer, Charcot or ischaemia, urgent referral to hospital-based medical care, ideally under an endocrinologist, diabetes specialist or surgeon or similar • For other patients, primary health-care team review every one to three months • Provision of irremovable device if available, or other offloading devices • Provision of written and oral education on self-management, including emergency contact details

Table 2: Stratification as per the IWGDF foot risk table, adapted on the basis of input from SGED–SSED, August 2015

PATIENT EDUCATION

When educating a patient, it is essential to assess their skills. In addition, if they are unable to see the top and bottom of the foot, identify who else could help carry out this assessment (e.g. a relative).

Patients should receive the following instructions:

- Inspect your feet daily, including between your toes. Use a mirror or ask a family member/caregiver to do this if you are unable to do so.
- Wash your feet daily with water at room temperature, including between your toes.
- Don't use hot water bottles in case of sensitivity loss, owing to risk of burns.
- Use lubricating oils or creams for dry skin, but not between your toes.
- Cut your nails straight across. Ideally use an emery board to cut your nails. Ask for help with this if necessary. Leave 1 mm of nail.
- Do not remove corns or calluses using a chemical agent, plaster or cutting tool (scalpel, etc.). Corns and calluses must be managed by trained staff.
- Always wear socks inside your shoes, ideally white socks, as they will show traces of blood in case of injury.
- Draw around your feet on pieces of cardboard. Cut the shapes out and insert them into your shoes to check that your shoes are long enough and broad enough.
- Before buying new shoes, try them on at the end of the day, as your foot might swell during the day due to oedema.
- Check inside your shoes for foreign objects before wearing them.
- Avoid walking barefoot.
- Ensure qualified health staff examine your feet regularly.
- Tell health staff immediately if a blister, cut, scratch or sore appears (16).

THREE: FOOTWEAR – INSOLES AND OFFLOADING

ACTIVE ULCERATION

Recommendation for active ulceration: Total contact cast, if available. This requires specialized training to apply safely.

Shown to be just as effective: Removable cast walker (also known as a CAM walker) *rendered irremovable*, with an accommodative insole on the plantar aspect of the foot.

A regular review mechanism must be in place. A physician must assume overall responsibility for patient care and identify the cause of ulceration.

The best evidence for healing active ulceration is for a total-contact casting (TCC) as the most effective way to offload a DFU. The TCC has been suggested as the “gold standard” method of offloading DFU after randomized controlled trials demonstrated 84–92% pressure reduction at the site of ulceration (10).

However, a TCC is difficult to apply and application requires a skilled practitioner. There is good evidence that a well-fitted removable cast walker **that has been rendered irremovable** is just as effective as a TCC (21). This is likely due to compliance, with one study of removable devices finding that only 29% of all steps were performed in the device (22).

A removable device can be rendered irremovable using a fibreglass wrap or similar locally-appropriate technique such as the use of plastic cable ties. The advantage of cable ties over wrapping in fibreglass is that the cast walker can be reused for the same patient (with the liner replaced or possibly just washed) (8). To protect the toes, the cast boot must be slightly longer than the foot.

The walker should extend to just below the knee and should be fitted with an appropriate pressure-redistributing insole for the plantar aspect of the foot (22). This insole can be used later in footwear once healing is complete.

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The cast walker can be modified using a heat gun to accommodate any deformity before application. A regular review mechanism prescribed by the treating physician should be in place for anyone fitted with any irremovable device.

Offloading occurs through the immobilization of the ankle and foot, which maintains total plantar contact throughout the stance phase, with pressure distributed over the entire plantar aspect of the foot. The rocker sole can assist with forward progression despite this lack of ankle or foot movement. Offloading also occurs through a firm fit that redistributes load to the device itself (9).

Figure 10: Removable cast boot

CHALLENGES RELATED TO TCCS AND CAST WALKER BOOTS

Many activities may be more difficult when wearing a TCC or cast walker boot. Driving, sleeping and maintaining a normal activity level have been reported as difficult. Education and explanation are critical to ensure compliance.

CONTRAINDICATIONS TO IRREMOVABLE DEVICES

Irremovable devices are contraindicated in cases of infection leading to exudate (liquid coming from the ulcer) and/or ischaemia (poor blood perfusion to the foot) (24). In such cases, alternative strategies that allow regular visual examination of the DFU should be considered. A simple removable cast walker is a possibility, as are certain other devices described below. Inability to ensure proper follow-up and review is a clear contraindication to an irremovable device.

FOOTWEAR TO PROVIDE TEMPORARY OFFLOADING OF THE FOREFOOT AND REAR FOOT

Temporary footwear that provides forefoot or rear foot offloading is an option as an interim measure or when an irremovable device is contraindicated.

These shoes move pressure away from the affected area by removal of the sole in that area (23). Angulation using anterior or posterior wedging helps redistribute the weight (13). Patients should not wear these temporary shoes long term as they offer limited protection. Permanent protective footwear must be obtained once wound healing is complete. The sole of this kind of shoe adds to leg length, which may disturb the patient's balance when they walk.

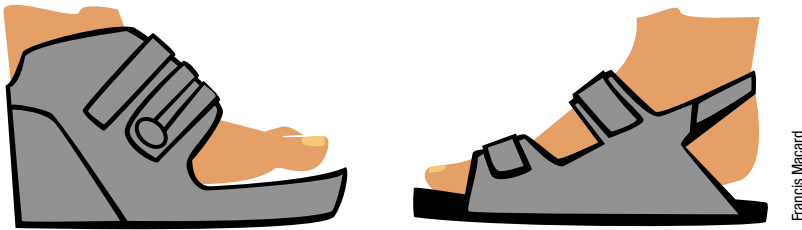


Figure 11: Offloading shoes

OFFLOADING – SUMMARY

- Compliance with offloading measures increases the likelihood of DFU healing, and current evidence favours the use of a TCC, or a removable boot rendered irremovable, as optimum offloading practice. The use of a TCC requires skills that rehabilitation professionals will need to acquire. Training with D-Foot incorporates this training and D-Foot is the ICRC's preferred partner.
- The second-best option is a removable cast walker with custom insole, with the patient being encouraged to use it as much as possible. This might be difficult for many patients.
- The third-best option is offloading shoes, properly fitted, with insoles.

PREVENTIVE MEASURES – FOOTWEAR

If a patient is in the high-risk category, preventive measures such as footwear and insoles should be applied. There is good evidence that the prescription of appropriate footwear and insoles as part of an outpatient clinic can help prevent diabetic foot ulceration. However, there is no evidence that footwear can heal an active diabetic foot ulcer. People at risk should never walk in bare feet, in socks or in normal thin-soled slippers.

Ill-fitting shoes are a common cause of skin trauma that precedes diabetic foot ulcers (12). Providing appropriate footwear can reduce the risk of DFU by reducing the likelihood of a skin lesion that could provide an opportunity for infection to occur (5).

Footwear and total-contact insoles should be considered in combination, with these two items together providing a total-contact interface for the at-risk foot. The purpose of total contact is to reduce both peaks of pressure and the magnitude of shear forces, as both are associated with skin lesions (25).

The focus should be on patients obtaining correctly-fitting shoes; it is often possible to obtain such shoes from special footwear shops, and PRCs should not automatically pay for or supply them. It is possible to develop relationships with local off-the-shelf footwear providers, ensuring that they maintain stocks of appropriate footwear. Initially, only people in the high-risk category are considered for special footwear.

Options for appropriate footwear include

- Sensible shoes from normal footwear shops.
- Orthopaedic stock shoes with extra depth or width, etc. and custom-made insoles.
- Customized (modular) or bespoke shoes made to measure or from casts.

These shoes (see picture) need to be acquired locally, as every patient requires individualized fitting. PRCs can explore options with local shoe makers regarding both stock and bespoke shoes.



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Figure 12: Shoe with flexible forefoot, to accommodate deformity

Example: In Ethiopia and Gaza, a number of these footwear options are available. Finding a suitable footwear provider is the first step, followed by negotiation of the working relationship with the PRC. Arrangements can be made for orthotists to measure and fit, with the supplier only carrying out the manufacturing, or the supplier can also carry out fitting. In-house footwear manufacture is a more complicated process, undertaken only if skilled personnel are available.

D-Foot International have supported footwear projects such as Flirt Bird. If they are present in a context, they would be a good choice of partner.

Footwear for people with diabetic neuropathy should:

- protect the foot
- relieve areas of excessive pressure
- reduce shock
- reduce shear
- accommodate deformities
- stabilize and support deformities (which includes immobilizing appropriate joints)

- accommodate an insole or an ankle-foot orthosis (AFO)
- be cosmetically acceptable
- be functional
- be long-lasting
- have a rocker bottom to decrease the plantar pressure/time integral.

Adapted from Ulbrecht & Cavanagh 2010 and Janisse & Janisse 2014

FOOTWEAR FITTING

The shape and volume of the fitted shoe must be correct, to ensure a good fit. Both feet should be measured, as it is common for there to be differences from one side to the other.

- Motor neuropathy can cause clawing of toes. This leads to the dorsum of the phalanges pressing against the toe box. Appropriate depth in the area of the toe box is required. Clawing of the toes can also make the metatarsal heads (MTH) more prominent, so offloading of the metatarsal heads using a total-contact insole may be important.
- The toe box must be sufficiently wide, to prevent toes being crushed together. Medial bunions or Taylor's bunions (lateral) can lead to excessive pressure from the shoes medially and laterally in the area of the metatarsal heads.
- Shoes must be of the appropriate length, which is around 1 cm longer than the foot. Remember that the foot elongates when the person is standing.
- The widest part of the foot is normally at the first metatarsal phalangeal joint (MPJ), and the shoe should be widest at this point.
- Depth of the mid-foot is important; the shoe should not apply pressure over the dorsum of the foot and should accommodate any insoles when achieving this.
- The width and shape of the heel box posteriorly must be such that the foot does not slip in the shoe.
- It should be easy to close the shoe, using laces or Velcro.
- The shoe should have a smooth lining, with no protruding stitching or other material.
- The shoe should have a strong sole to protect the foot from foreign bodies that could pierce the sole, and should have a mild built-in rocker sole.
- Slip-on shoes that slip over the heel should be avoided, as they have to be tight and short in order to fit (12).

ASSESSMENT OF FOOTWEAR

(Checklist for patients' existing shoes or after a fitting)

At each appointment, check the following for all footwear worn by a patient with diabetes, as feedback alone is not sufficient. Take this opportunity to educate the patient.

SUBJECTIVE	
Ask the patient if the footwear is	<ul style="list-style-type: none"> • Comfortable • Being used • Easy to put on and take off
OBJECTIVE	
Check fitting for	<ul style="list-style-type: none"> • Firm, snug fit throughout, but not tight • Appropriate length (extends 1 cm beyond longest toe when the patient is standing) • Appropriate width and depth, especially in toe box and at MTHs
Check inside the shoe for	<ul style="list-style-type: none"> • Soft, intact lining throughout • Foreign bodies
Check the general condition of the footwear	<ul style="list-style-type: none"> • Wear of the sole, especially lateral heel • Condition of the fastener and upper • Hygiene
Determine compliance	<ul style="list-style-type: none"> • Less-than-expected wear is a sign of poor compliance • Orthotic insoles in place (if provided)
Check for adequate protection	<ul style="list-style-type: none"> • Toes enclosed • Sole adequately firm

Table 3: Assessment of footwear

Adapted from McIntosh and Halford 2009

PREVENTIVE MEASURES – FOOTWEAR MODIFICATIONS

Preventive measures aim to stop ulcers from over-occurring. These measures can be applied to people at high risk of future ulceration.

ROCKER SOLES

A rocker sole allows movement through the stance phase of the foot and the shank position, without the need for the joints of the foot to move. A rocker sole can effectively reduce peak pressures. Its apex should be located just posterior to the point of desired offloading. Some of-the-shelf shoes already



have mild rocker soles, but for feet with deformities a custom rocker sole should be applied to a good-quality pair of shoes. The stiffness of the sole plays a critical role in preventing the rocker imposing additional loading on the affected area (12).

Figure 13: Rocker sole

EXTENDED SHANK

An extended shank may be made of steel or carbon and is placed within the structure of the sole of the shoe. It stiffens the shoe to prevent it bending during gait and can be used in conjunction with a rocker sole. By preventing bending of the shoe, the extended shank ensures that the entire plantar aspect of the foot is in contact with the ground during the stance phase. This reduces peak and average pressures (12).

LOCAL RELIEF

Areas of deformity such as claw toes can produce high localized pressures. Pockets of local relief can be provided by stretching the shoe using a leather-stretching tool and stretching fluid. This can be carried out in cases such as claw toes, prominent 1st or 5th metatarsal heads or other bony prominences (9).



G. Hainora

Figure 14: Leather-stretching tool

PREVENTIVE MEASURES – FOOT ORTHOSES

Foot orthoses should be considered in combination with footwear. This combination should not be seen as the first choice for healing an active DFU.

Foot orthoses are inserts fitted into the shoe. Total-contact foot orthoses can prove beneficial, particularly in the prevention of ulceration, or in the prevention of ulcer recurrence in patients with a history of DFU. This effectiveness is due to local peak pressure reductions achieved by spreading pressure more evenly over the entire plantar aspect of the foot.

Orthoses can be designed and manufactured to relieve a specific area on the plantar aspect of the foot, such as a site of high pressure or previous ulceration, by achieving partial offloading in this area. Such orthoses can be prescribed by an orthotist and/or a podiatrist following a comprehensive assessment of the patient, which should include gait analysis, assessment of the structure and function of the foot, and footwear assessment.

When motor neuropathy has left the metatarsal heads more prominent, a metatarsal dome or bar can be effective at reducing pressure in this region. This is often applied with a stiffer-soled shoe or a forefoot rocker. This stiffener prevents phalangeal dorsiflexion, which is associated with higher pressures in the metatarsal head region. The forefoot rocker allows forward progression despite the limitation to dorsiflexion.

Foot orthoses may be off-the-shelf or custom-made. What is of critical importance is that they be a good fit for the foot shape of the individual. This reduces pressure and shear forces on the plantar aspect of the foot.

If a patient has a history of Charcot foot, significant deformity, partial foot amputation or neuropathy, custom insoles are more appropriate.

The purpose of a foot orthosis for people with diabetes is to:

- cushion and protect the foot
- reduce areas of high pressure through pressure redistribution
- provide shock attenuation
- support and protect healed fracture sites through immobilization
- reduce shear forces
- control and stabilize flexible deformities
- limit motion of affected joints
- accommodate fixed deformities.

The orthosis should be covered with a soft, thin material.

Adapted from Cavanagh 2010 and Janisse & Janisse 2015

Casting and the taking of foot impressions for custom insoles should be done with care, as it is possible to damage the foot:

- residual plaster of Paris left behind between toes can act like gravel and damage neuropathic feet during walking
- firm pressure to push feet into impression boxes or onto a casting bladder can damage high-risk feet
- people with active ulcers should not be asked to walk without shoes or socks for gait analysis
- active ulcerations should be protected during all stages of assessment, casting and fitting, to prevent the introduction of infection.

Rigid foot orthoses are not appropriate and are contraindicated for people with diabetes (12). Full-length semi-rigid or accommodative insoles are more appropriate. Ethyl vinyl acetate (EVA) of different densities is a suitable material, as it is important that the insole be firm enough to resist structural compression but that the interface be soft enough to prevent high peak pressures. A soft cover made from soft EVA or shammy leather can be useful for assessing the fit later, as the foot will leave an impression in it. The edges of the insole should be continuous with the footwear, with no ridges that would result in areas of high

pressure. A soft cover made from soft EVA or shammy leather can be useful for assessing the fit later, as the foot will leave an impression in it. The edges of the insole should be continuous with the footwear, with no ridges that would result in areas of high pressure.



Figure 15: Insole for pressure redistribution

Published literature supports orthotic intervention as an integral aspect of the treatment regime for patients with diabetic foot disease (26). One study found improvements in both the physical and the mental health of patients who had received orthotic intervention (27).

CHARCOT FOOT

Charcot foot (or neuropathic osteoarthropathy) is a serious condition characterized by varying degrees of bone and joint disorganization secondary to underlying neuropathy, trauma and changed bone metabolism. Disorganization occurs typically in the mid foot but can occur in the fore or hind foot (13).

The classic presentation is a mid-foot collapse that results in a “rocker bottom foot” (28). See Figure 16 below.



Figure 16: Rocker bottom foot and plantar hyperkeratosis/callus

The clinical presentation of a Charcot foot is an acute local inflammation, with warmth (skin 2° C hotter than contralateral foot) and swelling often being the first symptoms noticed. A lack of pain due to neuropathy can mean individuals continue to ambulate despite fracture, bone destruction, subluxation, dislocation and deformity (28).

In the case of acute or active Charcot foot, NICE guidelines (2016) advocate immediate offloading through crutches or wheelchair use and application of a TCC to offload the foot and reduce the risk of spontaneous fracture and gross deformity. Patients need to be closely followed up at PHC and/or specialist/secondary-care level. In the absence of a TCC, a removable walker can be made non-removable and the addition of an insole can make the device total-contact to achieve offloading (13). Effort should be made to ensure an intimate total-contact fit of the cast walker. Examination should be initially after three days and then weekly (28).

Non-active Charcot foot is characterized by a skin temperature difference of less than 2° C, an X-ray showing bone healing and a reduction in redness (13). A Charcot restraint orthotic walker (CROW) is indicated, to immobilize and partially unload the foot during early rehabilitation. The CROW achieves total contact with a bivalve AFO, with anterior and posterior sections, lined with a material such as Plastazote™ or soft EVA. It is indicated for a period of 2–3 months (29).



A. Bourgeois/Geneva University Hospital

Slow and careful rehabilitation is needed, beginning with just a few short steps per day within parallel bars, with partial weight being borne by the upper limbs. A careful and gradual progression of total steps is needed to prevent relapse. Monitoring for relapse must be undertaken, with careful temperature assessment and examination for swelling daily. This should be carried out under the supervision of a physiotherapist.

Figure 17: A bivalve custom-made CROW

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- Dr Jorge Correia, senior resident, patient therapeutic education, Geneva University Hospitals
- Alain Lacraz, physiotherapist, Geneva University Hospitals
- Christophe Paoli, podiatrist, Geneva
- Guy Miganne, specialist nurse, diabetes clinic, Geneva University Hospitals
- Dr Bettina Peter-Riesch, diabetologist, consultant, Geneva University Hospitals

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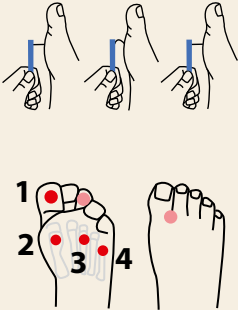
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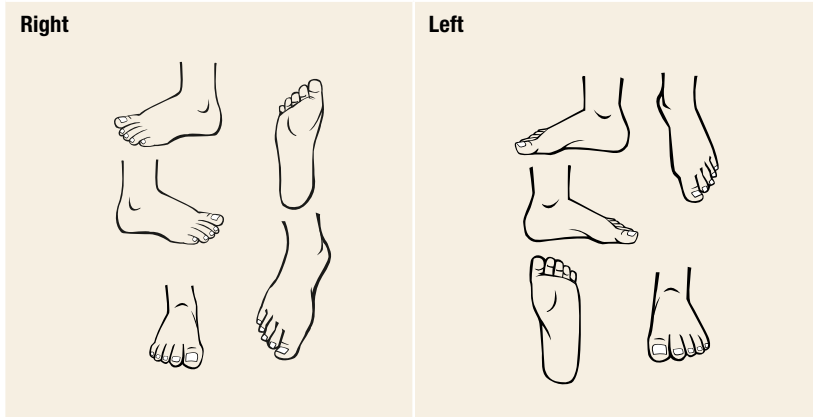
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ANNEX: DIABETIC FOOT ASSESSMENT FORM

DIABETIC FOOT ASSESSMENT

TITLE	RESULTS	REMARKS
1 – Type of diabetes	<input type="radio"/> Type 1 <input type="radio"/> Type 2 <input type="radio"/> Gestational <input type="radio"/> Unknown	
2 – History of previous foot ulceration? Healing time of ulcer if known (months)	<input type="radio"/> Yes <input type="radio"/> No <input type="text"/> (from 1 to 24)	
3 – Signs of peripheral neuropathy Ability to feel monofilament test at one of these four main sites:	<input type="radio"/> Neuropathy <input type="radio"/> Intact sensation	
	1. <input type="radio"/> Yes <input type="radio"/> No 2. <input type="radio"/> Yes <input type="radio"/> No 3. <input type="radio"/> Yes <input type="radio"/> No 4. <input type="radio"/> Yes <input type="radio"/> No	
4 – Foot condition 1. Wound 2. Ulceration 3. Gangrene 4. Rest pain 5. Cellulitis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No	
If yes to 2. Ulceration, measure diameter: _____ (numeric field, mm)		
Indicate the results regarding Points 1 to 5 on the drawing, using the abbreviations W/U/G/RP/C		

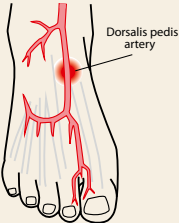


If you answered “Yes” to one of Points 1 to 5 in the “Foot condition” section, referral to medical care is required if the person is not already under care.

Indicate the person’s status:

- HSU under care Referral

<p>5 – Foot deformity</p>	<ul style="list-style-type: none"> <input type="radio"/> Deformed Nails <input type="radio"/> Callus <input type="radio"/> Hallux Valgus <input type="radio"/> Claw Toe <input type="radio"/> Hammer Toes <input type="radio"/> Pes Cavus <input type="radio"/> Rocker Bottom Foot <input type="radio"/> Charcot Foot <input type="radio"/> Fungal Infection <input type="radio"/> Macerated Toe Space <input type="radio"/> Skin Fissures 	
<p>6 – Temperature</p>	<p><input type="radio"/> Cold <input type="radio"/> Hot <input type="radio"/> Normal</p>	
<p>If Cold:</p> <ul style="list-style-type: none"> - Pale - Dark coloration - Hair loss - Change in skin texture 	<ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No 	
<p>If Hot:</p> <ul style="list-style-type: none"> - Red - Swollen 	<ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No 	

<p>7 – Dorsalis pedis foot pulse:</p> 	<p> <input type="radio"/> Present <input type="radio"/> Absent <input type="radio"/> Unsure of finding </p>	
<p>8 – Footwear type</p>	<p> <input type="radio"/> None <input type="radio"/> Open shoe <input type="radio"/> Closed shoe </p>	
<p>If wearing footwear, check the following</p> <p>Subjective: Ask the person if their footwear is</p> <ul style="list-style-type: none"> – Comfortable – Being used – Easy to put on and take off <p>Objective:</p> <p>1. Check fitting for</p> <ul style="list-style-type: none"> – Firm snug fit throughout, but not tight – Appropriate length (1 cm beyond longest toe when standing) – Appropriate width and depth <p>2. Check inside the shoe for</p> <ul style="list-style-type: none"> – Soft intact lining throughout – Foreign bodies <p>3. General condition of the footwear</p>	<p> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No </p> <p> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No </p> <p> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No </p> <p> <input type="radio"/> Good <input type="radio"/> Acceptable <input type="radio"/> Worn out </p>	

IWGDF risk classification system (see table)		○ 0 ○ 1 ○ 2 ○ 3
Category	Characteristics	Frequency of review
0	No peripheral neuropathy, no signs of peripheral arterial disease, no other risk factors	Once a year, conduct patient education on self-management
1	Peripheral neuropathy or arteriopathy (without calluses or deformities), unable to self-care or on dialysis	Once every 6 months, check footwear and/or insoles, conduct patient education on self-management
2	Peripheral neuropathy with peripheral arterial disease and/or a foot deformity	Once every 3-6 months, check footwear and/or insoles, conduct patient education on self-management
3	Peripheral neuropathy and a history of foot ulcer or lower extremity amputation	Once every 1-3 months, check footwear and/or insoles, conduct patient education on self-management

CONCLUSION

Assessment date:

Proposed follow-up date, decided on the basis of the assessment:

Approved by

PICTURES FOR DROP-DOWN LIST ON ASSESSMENT FORM

Deformed nails, calluses, hallux valgus, toe deformities, foot deformities, macerated toe space, skin fissures



Hallux valgus, deformed nail, hammer toe



Callus and rocker bottom foot/Charcot foot



Lateral foot ulcer and rocker bottom foot/Charcot foot






Plantar ulcer



Nail deformation and necrosis

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