



People.Health.Care.

The Diabetic Foot Syndrome (DFS)

Every foot matters.



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Check and monitor
your vascular
status frequently.

CHAPTER 1

The Diabetic Foot Syndrome (DFS)

The diabetic foot is a major complication and affects medical, social and economic areas worldwide. The reported frequency of ulceration and amputation varies considerably. This may be due to differences in diagnostic criteria as well as regionally specific social, economic and health-related factors.

Neuropathy is a frequently encountered complication of diabetes. The reported prevalence of diabetic peripheral neuropathy ranges from 16% up to 66%.

Diabetic peripheral neuropathy is an impairment of normal activities of the nerves throughout the body and typically can alter all different nerval qualities: autonomic, motor and sensory function.

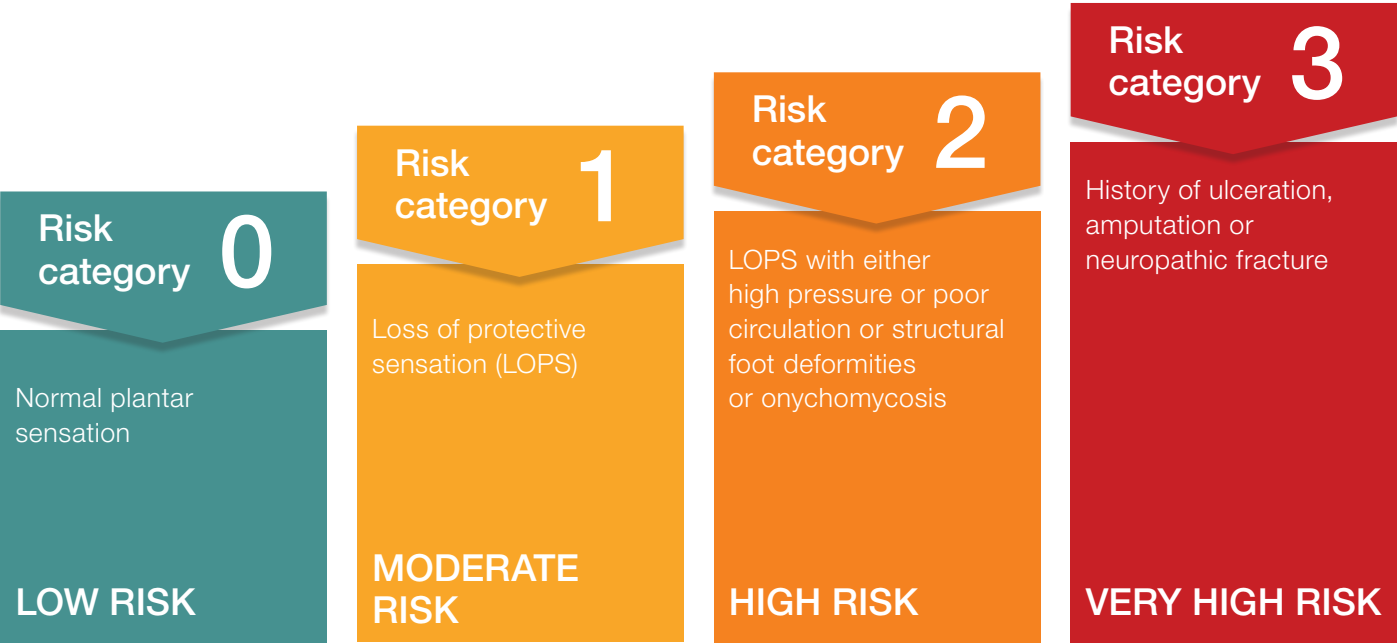
All people with diabetes should be screened and placed in the appropriate risk stratification which includes the

clinical pathway for prevention and treatment. Members of the team and necessary services are foot care nursing, diabetes education, pedorthists, a skilled wound care team, physicians, podiatrists, prosthetics, home care and counselling, among others.

There is a very specific risk situation in any patient suffering from diabetes mellitus with an existing foot complication.

The IDF (International Diabetes Federation), the world's leading organisation concerning diabetes, was incorporated in 1950 as an international not-for-profit organisation and provides the legally binding purpose which is encapsulated in the vision "Living in a world without diabetes" by promoting diabetes care, prevention and a cure worldwide.

A graduation is given by the IDF risk categories:



IDF risk categories of DF

Diabetes mellitus and diabetic foot: facts and numbers

Number of people with diabetes per region (in millions) in 2017

- North American & Caribbean
- Middle East & North Africa
- South & Central America
- Western Pacific
- Europe
- Africa
- South East Asia



425,000,000

diabetics worldwide

00.07

Every 7 seconds someone dies from diabetes.

1 in 2

adults with diabetes are undiagnosed.

1 in 11

adults has diabetes.

2 out of 3

diabetics live in urban areas.

00.20

Every 20 seconds someone undergoes an amputation.

Every 3rd to 4th diabetic will develop a DFS during his lifetime!

The lifetime risk of people with diabetes to develop a foot ulcer is 34%.

More than 50% of diabetic foot ulcers become infected.

20% of diabetic foot infections result in amputation. Diabetes contributes to approximately 80% of the 120,000 non-traumatic amputations performed yearly in the United States. More than half of those with heel osteomyelitis will undergo high-level amputation.



Diabetes causes damage to all qualities of nerves throughout the body when blood glucose levels, blood pressure and some other parameters are too high. This can lead to problems with digestion, erectile dysfunction and a number of other functions. Among the most commonly affected areas are the extremities, in particular the feet. Nerve damage in these areas is called peripheral neuropathy, and can lead to pain, tingling or other discomfort, and complete loss of feeling.

Loss of feeling is particularly important because it can allow injuries to go unnoticed, leading to serious damages, infections and possible amputations. People with diabetes carry a risk of amputation that may be more than 25 times greater than that of people without diabetes.

Polyneuropathy (PNP) is a generic term for certain changes of the peripheral nervous system that always affect several nerve qualities. In diabetic PNP, all qualities of the peripheral nervous system are affected. Three different manifestations can be described:

1

Sensoric neuropathy

The damage of sensitive nerve fibres occurs to multiple sensory disorders:

- itching, tingling or burning
- numbness in legs and feet
- sensoric disturbances (for touch, pressure and proprioception)
- changed temperature perception
- sensoric disturbances of pain (hypoesthesia, anaesthesia)

Patients are at high risk of unnoticed foot injuries or trivialise “painless” wounds!

2

Motoric neuropathy

Caused by damage to the motoric nerve fibres there is a destabilisation and deformation of the feet with changes in gait:

- weakness and atrophy of the small foot muscles
- relocation of subcutaneous fat pads at the bale
- deformation of the toes/the entire foot
- changes in pressure distribution lead to callus formation on toes and sole

Increased pressure can cause ulcerations (malum perforans)!

3

Autonomic neuropathy

Disturbances of the autonomic system affect the regulation and function of the blood vessels as well as sebaceous and sweat glands:

- dilated vessels (rosy skin colour) and formation of arteriovenous shunts, passing the blood flow throughout the capillary system
- red and warm foot (non-recognition of arterial disturbances)
- disturbed oxygen supply
- reduced sweating, creating dry, flaky skin, tears and fissures
- increased risk of wound infection
- formation of oedema in the area of the back of the foot (possible restrictions in joint function)

Advanced autonomic neuropathy of the foot is able to cause damages to the bones and joints, to cause wounds and to cause fractures of foot bones up to a collapse of the foot skeleton (Charcot foot)!

Pathophysiological process and risk definition

Progress of neuropathy has been described by the IDF Clinical Practice Recommendations on diabetic foot in three categories:

A

The first determinant in the escalation of the risk categories, and thus leading to an increased risk of complications, is the loss of sensation (peripheral neuropathy). This deficit increases the patient from risk category 0 to risk category 1. This is further increased to risk category 2 when found in conjunction with PAD, structural foot deformities or onychomycosis.

The sensory neuropathy is assessed using the 5.07 monofilament (MF) exerting 10 grams of pressure on the foot to test sensation. Other tests might need to be performed if the patient can feel the MF, such as a 128 Hz tuning fork (vibration sensation), neuro tip (pain sensation) and temperature sensation.

Once sensation is lost, it is not just stepping on a piece of broken glass, a drawing pin, other objects or wearing improper footwear that puts these patients at risk; it is also the repetitive, constant stress of walking that puts the neuropathic foot at risk of ulceration.

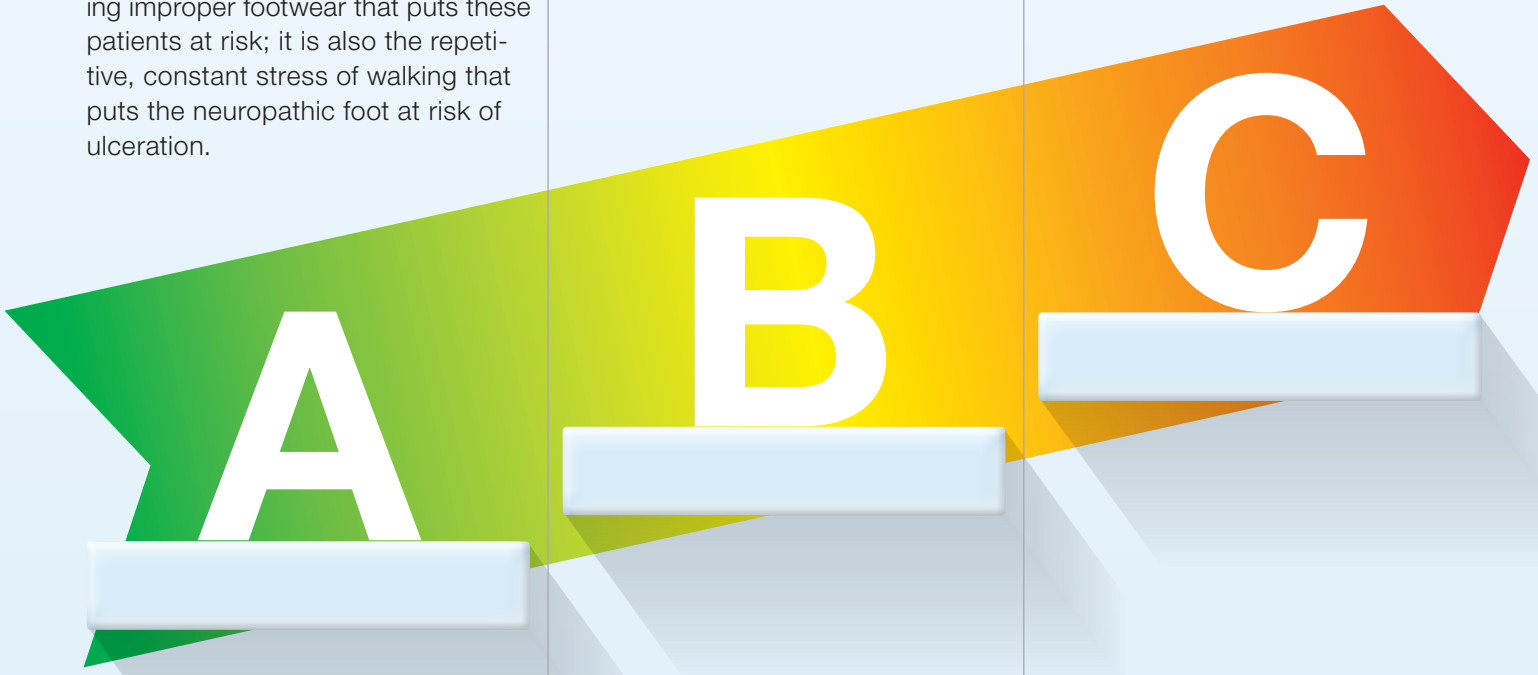
B

As motoric neuropathy progresses and the small muscles of the foot denervate, we will see that weakness, atrophy and imbalance in the intrinsic musculature of the foot causes the high risk Intrinsic Minus Foot. Flexion of the interphalangeal joints and hyperextension of the metacarpophalangeal (MTP) joints results in clawing of the toes which depresses the metatarsal heads and pushes the metatarsal fat pads distally so they no longer provide cushioning over the bony prominences of the metatarsal heads. Muscle imbalances lead to foot deformities which change the biomechanics of the foot subjecting it to the repetitive stress.

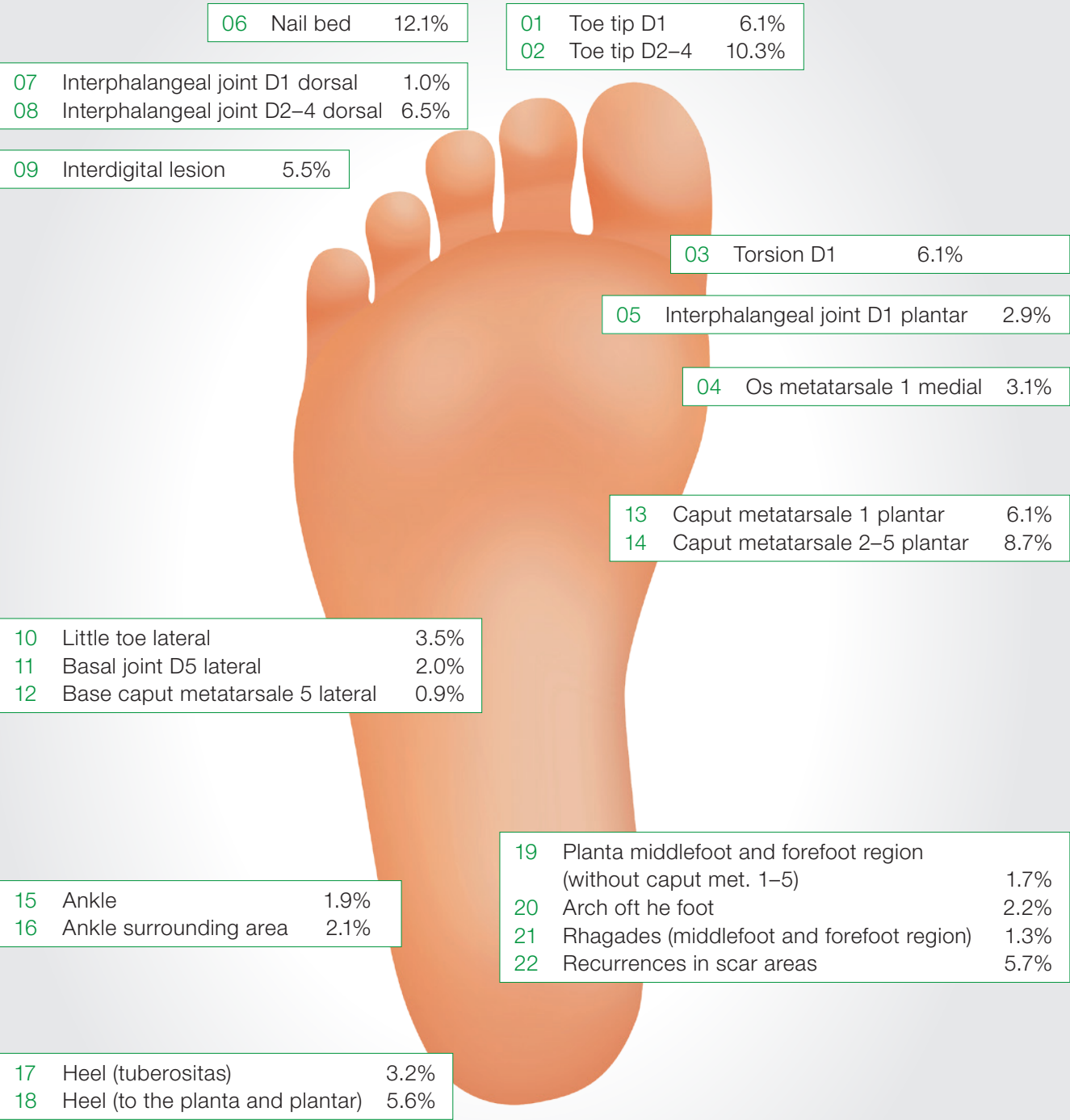
The repetitive, constant pressure of walking may cause calluses which can ulcerate and then become infected.

C

As neuropathy progresses, the small, unmyelinated nerves that are responsible for pain and temperature will be affected. Patients will complain of pain in the feet (burning or lancinating in nature) and either hot or cold feet as the neuropathy advances.



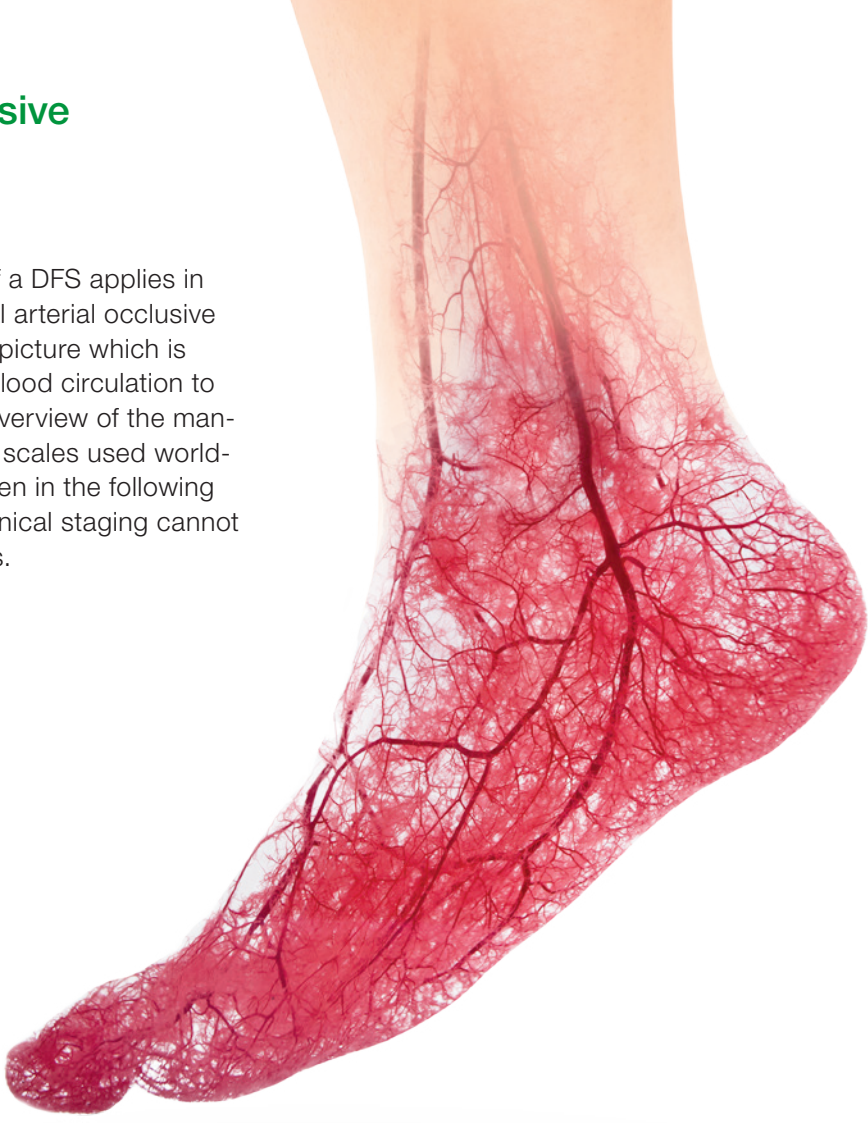
Localisation of lesions on the foot in Central Europe



(Acc. to Hochlenert et al. 2014)

Peripheral arterial occlusive disease (PAOD)

Another reason for the emergence of a DFS applies in addition to polyneuropathy peripheral arterial occlusive disease (PAOD). It refers to a clinical picture which is characterised by a reduction of the blood circulation to the limb due to atherosclerosis. An overview of the manifestation and severity of AOD by the scales used worldwide (Fontaine and Rutherford) is given in the following table. In case of existing PNP, this clinical staging cannot be used due to the lack of symptoms.



Fontaine		Rutherford		
Stage	Clinical manifestations	Grade	Category	Clinical manifestations
I	asymptomatic	0	0	asymptomatic
IIa	can walk > 200 m	I	1	mild claudication
IIb	can walk < 200 m	I	2	moderate claudication
		I	3	severe claudication
III	ischaemic pain at rest	II	4	ischaemic pain at rest
IV	ulcer, gangrene	III	5	small area of necrosis
		III	6	large area of necrosis

Fig.: Grading and staging of PAOD

If PNP and PAOD get together

It has to be pointed out that the typical classification in PAOD cannot be applied to DFS if diabetics additionally suffer from a PNP and so do feel neither stress nor rest pain. Such patients become symptomatic very late.

- The current classifications are based on the risk assesment of the endangered extremity [Hochlenert et al. 2014]:
- **wound criteria**
 - **severity of circulation disturbance (ischaemia)**
 - **severity of a foot infection (that may present)**

A complete and exact survey of vascular status plays an important role especially in diabetics. If PNP and a PAOD occur together, an unproblematic wound healing process without perfusion-enhancing actions is highly unlikely.

Polyneuropathy (PNP) is a generic term for certain changes of the peripheral nervous system that always affect several nerve qualities. In diabetic PNP, all qualities of the peripheral nervous system are affected.

PNP + PAOD

If **PNP** and **PAOD** get together, the wound healing processes are significantly disturbed and there is **a high risk of wound infection and amputation!**

CHAPTER 3
From diagnosis to therapy in DFS



► 1. Foot inspection

The foot should be inspected for bony prominences or any visual deformities. A foot deformity could be hammer toes, bunions, a prominent metatarsal head or a Charcot foot. Patients with neuropathy and deformity have a more than twelvefold increased risk of ulceration than patients without neuropathy.

It is important to recognise that foot deformities alone do not cause ulceration. However, when combined with sensory neuropathy, the conditions are favourable

for ulcer formation. Some deformities are not visible to inspection.

Limited joint mobility (LJM) is just as important a predictor for ulceration as a visible deformity.

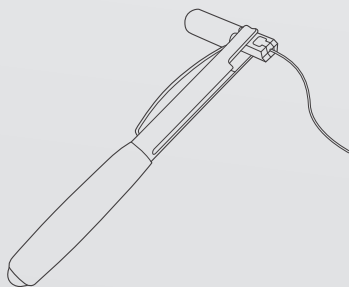
This is also an opportunity where prophylactic surgery can prevent foot ulceration [International Diabetes Federation].

Wagner-Armstrong classification

Armstrong stage	Wagner grade					
	0	1	2	3	4	5
A	pre or post ulcerative foot	superficial wound	wound up to the level of tendons or capsule	wound up to the level of bones and joints	necrosis of parts of the foot	necrosis of the entire foot
B	with infection	with infection	with infection	with infection	with infection	with infection
C	with ischaemia	with ischaemia	with ischaemia	with ischaemia	with ischaemia	with ischaemia
D	with infection and ischaemia	with infection and ischaemia	with infection and ischaemia	with infection and ischaemia	with infection and ischaemia	with infection and ischaemia

2. Clinical diagnostics

A Touch-pressure sensation

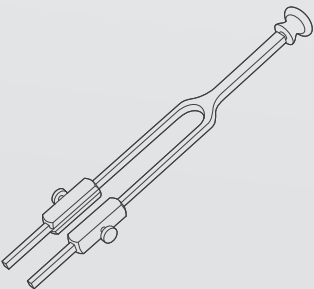


Using the 10 g monofilament assess the four main areas on the plantar surface of the foot (avoiding areas of callus).

Place the monofilament on each area of the foot PERPENDICULARLY until the monofilament buckles, and hold for 2 seconds each time with the patient's eyes closed and answering "yes" each time they feel it. Preferred sites for testing are the plantar surfaces of the 1st, 3rd and 5th metatarsal heads and the plantar surface of the hallux.

The diagnosis of neuropathy is determined if the patient does not feel 1 out of 4 areas tested.

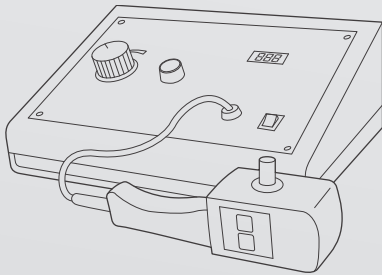
B Testing for vibration



Using a 128 Hz tuning fork.

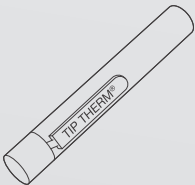
1. Ask the patient to close their eyes.
2. Put the patient's feet on a flat surface and tap on the tuning fork.
3. Place the vibrating fork on the patient's distal hallux (big toe) joint and ask them if they can feel vibration (show the patient on a bony prominence on their hand first).
4. Have the patient answer yes or no when asked if they can feel the vibration.
5. If they cannot feel vibration on the hallux continue checking bony prominences moving proximally until the patient feels the vibration.

C Measure vibration perception threshold (VPT)*



Measure VPT using electromechanical instruments such as the Biothesiometer or Vibrometer. A VPT value of >25 V in at least one foot has been associated with a higher cumulative risk of neuropathic ulceration. Values between 16 and 24 V indicate intermediate risk, and values <15 V represent low risk and is considered normal.

D Test temperature sensation



Test temperature sensation with Tip Therm or test tubes, one with cold water (5 to 10 °C) and one with warm water (35 to 45 °C). Put on the dorsum of the patient's foot directly on the skin and ask the patient what they feel. Grade the temperature sensation testing as normal, weak or loss of temperature sensation. Please remember that temperature sensation is lost in conjunction with pain sensation (small, unmyelinated nerves) so if the patient has lost temperature sensation then pain is also usually lost.

E Pain sensation

Pain is a common and sometimes severe manifestation in people with diabetes. Most patients with painful diabetic peripheral neuropathy (PDPN) complain of various kinds of painful sensation, such as stinging, burning, lancinating pain, electric-like shocks as well as aching pain in the lower extremities. Additionally, the loss of protective sensation is the important mechanism in the development of foot impairment.

Evaluation of pain
The total symptom score system (TSS) is a recommended diagnostic method.

Symptom		Severity			
Frequency	no	mild	moderate	severe	
occasional	0	1.00	2.00	3.00	
often	0	1.33	2.33	3.33	
persistent	0	1.66	2.66	3.66	

Note: The enrolled symptoms include numbness, cutting, burning and stinging pain. TSS score = summation of four feelings, ranged from 0 to 14.64. TSS > 3 is considered positive.

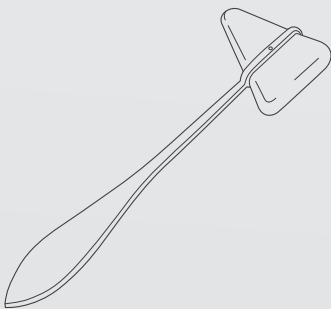
Another simple method to assess pain is the ID pain scale.

Issues	Yes	No
1. Did the pain feel like pins and needles?	+1	0
2. Did the pain feel hot/burning?	+1	0
3. Did the pain feel numb?	+1	0
4. Did the pain feel like electric shocks?	+1	0
5. Is the pain made worse with touch of clothing or bed sheets?	+1	0
6. Is the pain limited to your joints?	-1	0
Total score		

Criteria of ID pain scale. Results' evaluation:

Total score	-1	0	1	2	3	4	5
Judge-ment	Exclude neuralgia	Not all exclude neuralgia	Consider neuralgia	Highly consider neuralgia			

F Check for reflexes



1. Check the patient's ankle reflex and patellar reflex on the Achilles tendon or ligamentum patellae with a percussion hammer. This may be weak in the elderly so it is not a specific test.
2. Assess for motor neuropathy by testing the splay of the lesser digits, and flexion and extension of the big toe and ankle. As weakness progresses up the leg from intrinsic musculature to extrinsic musculature, ask the patient to walk on their toes and heels to assess extrinsic muscle strength.

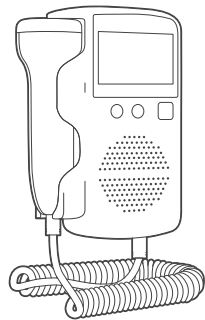
This important component of neuropathy often goes undetected because practitioners do not look for it. Motor neuropathy correlated with intrinsic muscle atrophy plays a role in the weakness of the digit stabilisers progressing to ankle and knee weakness.

Overall gait instability will affect the patient's ability to walk and manage their blood glucose. They may also have an increased risk of falling.

► 3. Vascular diagnostics

The basic diagnosis represents the clinical examination with the pulse status. If possible (not applicable for severe sclerosis of the arterial muscle layer – media sclerosis), the ankle brachial pressure measurement should be done by Doppler ultrasound.

In addition, the examination includes, besides the colour-coded duplex sonography, the magnetic resonance angiography (MRA) or digital subtraction angiography (DSA), mostly in intervention standby.



CHAPTER 4

Importance of self-care and patient's recommendations

An important step in including the patient in the whole treatment process is to introduce self-care, to empower the patient in their social surroundings and to gain the patient's control over their specific conditions.

Education

Due to a lack of a normal pain response, neuropathic individuals will ignore signs of injury and focus on their task at hand. Lack of pain feedback in the presence of injury creates difficulty with patient adherence and

commitment to self-inspection protocols. Intense education and foot care knowledge is necessary to reduce foot complications.

Rules of conduct

Patient should:

- check shoes before putting on
- change shoes daily if able to, as different shoes distribute pressure differently
- not check bathwater with their feet
- clean feet daily
- check feet daily
- keep feet moisturised with creams but not between the toes
- never walk barefoot
- wear shower shoes

Self-care is an important key

Reduce treatment time and costs

Patient empowerment is fundamental

Optimise treatment outcomes

Patients gain control over their condition

Improve patients' lives



Importance of skin integrity and skin care

Wound patients are vulnerable to peri-wound skin damage. This can lead to increased wound size, delayed healing and increased levels of pain. Consequently, healthcare costs may increase

and the patient's quality of life may be reduced. Careful monitoring and ongoing assessment of both the wound and peri-wound skin will aid in identifying skin changes and treatment options.



Prevent amputations. Relieve suffering.

Pathogenesis of diabetic neuropathy is multifactorial. Drug treatment to prevent the occurrence of neuropathy (primary prevention) or to reverse or halt the progress of existing neuropathic damage (secondary prevention) has been extensively studied with very little or no success.

Good glycaemic control in all types of diabetes has shown promising results. The Diabetes Control and

Complications Trial (DCCT) of type 1 diabetes has conclusively shown a risk reduction of 69% in the primary prevention of neuropathy in good vs. conventional glycaemic control.

Intensive therapy also showed a risk reduction of 57% in the secondary prevention of neuropathy [Diabetes Control and Complications Trial Research Group].

The main treatment components in DFS are:



Diabetes control is at the top of all DFS management. Without this, all other measures become meaningless.

Effective care for diabetic feet:

STEP

Debridement/
wound bed preparation

1

For every dressing change, the wound also has to be cleaned.

Debrisoft Lolly has been developed for the debridement of deep wounds even of surgical origin.

In superficial wounds **Debrisoft Pad** allows quick, easy and painless debridement.

Wound Care

2

Diabetic foot ulcers are typically deep exuding wounds. The hydro-fibre dressing **Suprasorb Liquacel** is a wound filler effectively able to protect the wound edge from exudate to avoid maceration.

In case of infection, wound fillers with antimicrobial properties can be used.

For heavily exuding wounds the use of superabsorbent dressings like **Vliwasorb Pro** is recommended.

Offloading

3

As already reported, the essential pressure relief and distribution can be supported by cushioning elements. A recent, effective method is "foot felting".

Felting pads such as **Cellona** could be used for this technique.

Furthermore, an orthopaedic supply is strongly required with a special footbed.

(Acc. to Hochlenert et al. 2014)



Stage-related wound therapy

To maintain or to restore skin integrity is the most important aim in the therapy of a diabetic foot ulceration as well as in prevention of any lesion.

For successful treatment, a systematic approach is necessary. L&R is able to support each therapeutic step with modern, effective solutions for wound healing.



1 Debridement

Effective wound-bed preparation is a basic requirement for a successful healing process. Therefore, the removal of debris is the first step in wound management. Debridement can be done by mechanical, surgical, autolytic or other techniques.

The most effective form of debridement is surgical debridement, e.g. by scalpel. The aim is the total removal of any non-vital structure. Clearly, as part of infection management the removal of all necrotic material, slough and devitalised tissue is crucial.

Effective and technically simple debridement can be carried out via the use of a monofilament fibre pad, such as Debrisoft Pad or the Debrisoft Lolly, which was developed for use in deep and post-surgical wounds.

2 Wound Care

The choice of the appropriate wound dressing is strongly influenced by the wound diagnosis and anamnesis. To assess the risk for a wound infection, the use of the so-called W.A.R. score (wounds at risk score) is able to assist in the decision-making process to use antimicrobial treatment options.

The earlier foot lesions are treated, the more effective the infection prevention.

Modern wound dressings are intended to maintain a physiological wound environment with a constant temperature to ensure and protect the wound from any damage or microbial burden and to allow gas exchange. Depending on the degree of exudation, an appropriate exudate management is important.

3 Offloading Risk-adapted treatment

The mainstay of therapy for DFS is the offloading of pressure.

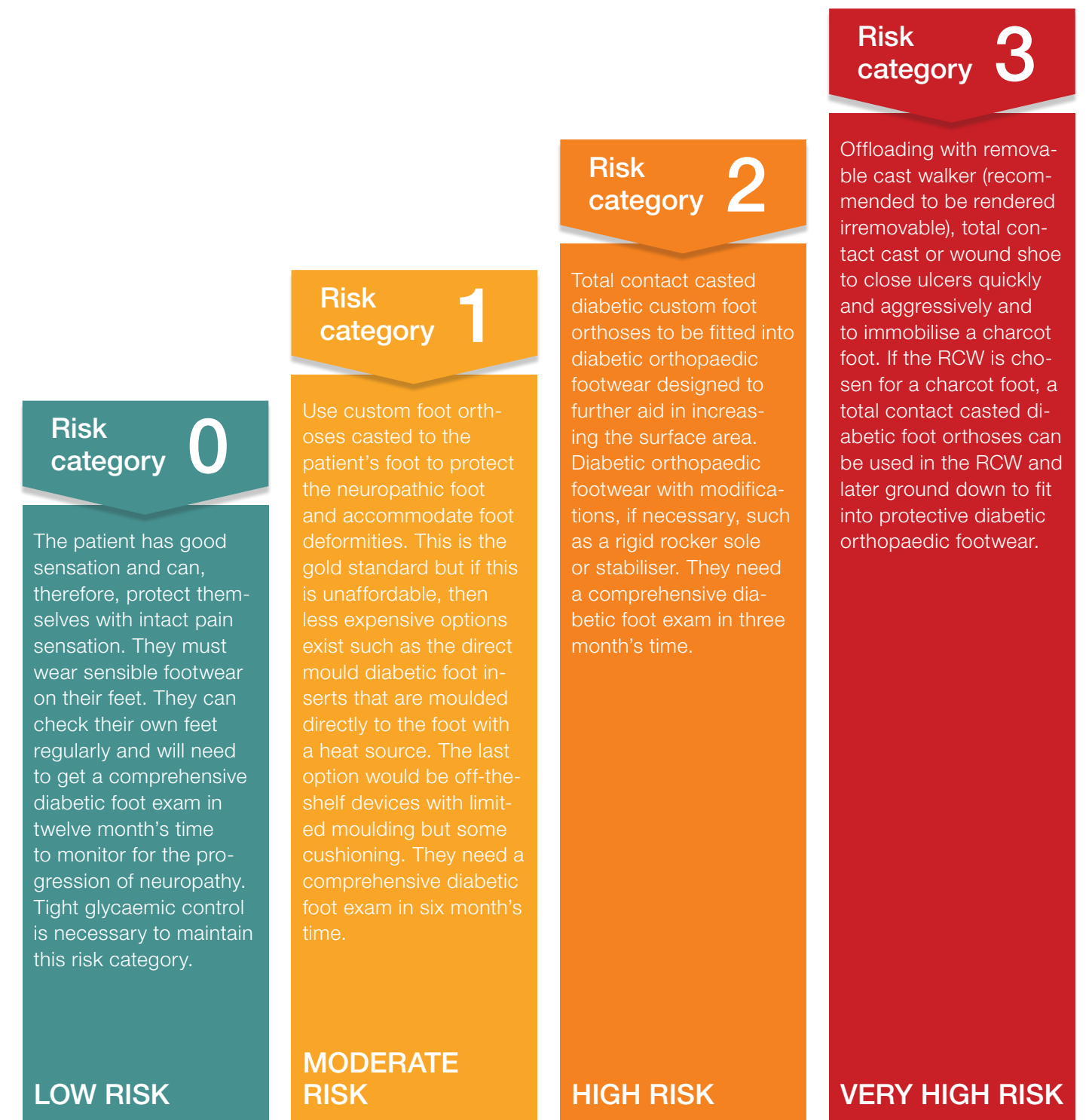


Fig. Risk categories and treatment options
[IDF Clinical Practice Recommendations on the Diabetic Foot]

3 Offloading Risk-adapted treatment

A new and effective method for pressure relief and offloading is “felting”. Thereby, the pressure relief or distribution is supported by cushioning elements (e.g. Cellona) which are applied to the skin around the ulceration. This technique is used to keep the wound out of the weight-bearing zones at every stage of movement.

(Hochlenert, D., Engels, G., Morbach, S.: Diabetic Foot Syndrome. From Entity to Therapy. Springer Medizin-Verlag, Berlin, Heidelberg, 2018)



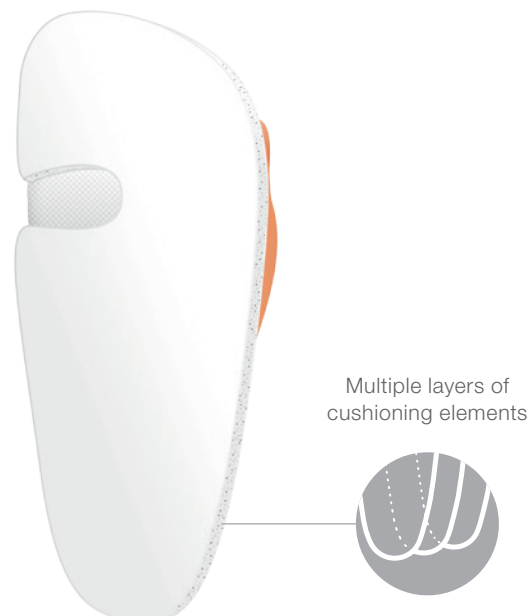
A Wound dressing



B Instep cushioning

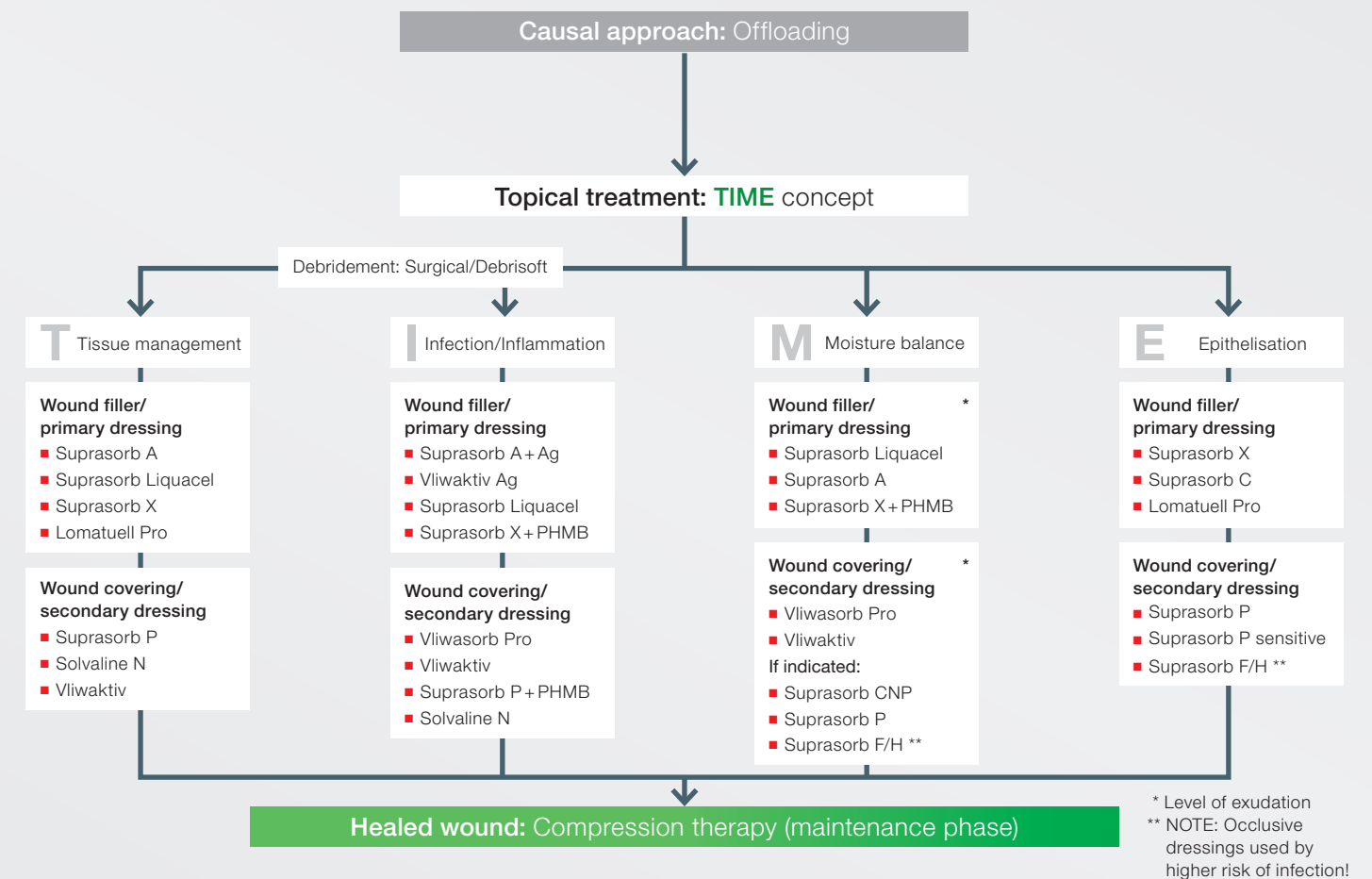


C Total offloading with Cellona Felt



D Offloading with felt or Complex

Wound management pathway diabetic foot ulceration:



Selected dressing compounds at a glance

Silver and PHMB:

In critically colonised and infected wounds the reduction of the microbial load is essential. Antimicrobial substances such as silver and polyhexamethylene biguanide (PHMB) are able to reduce the bioburden in the wound area. Due to its very good tolerability, PHMB is superior for the application.

PU foam dressings:

These are made of polyurethane material and are able to absorb and store exudate. Some foams additionally demonstrate antimicrobial properties.

Antimicrobial HydroBalance wound dressings (Suprasorb X + PHMB):

They are suitable for rehydration in low to medium exuding wounds and are able to reduce the microbial load. For wound covering, a combination with special compresses (e.g. Solvaline N) can be recommended.

Absorbent calcium alginate dressings:

For heavily exuding wounds, alginate dressings with or without antimicrobial silver are used to absorb exudate and to reduce the microbial bioburden, such as in combination with absorbent compresses (e.g. Vliwazell) or superabsorbent wound dressings such as Vliwasorb Pro.

Activated carbon and antimicrobial wound dressings:

In malodorous wounds they are able to reduce the emissions as well as the microbial load.

Hydrofibres (e.g. Suprasorb Liquacel):

The fibres made of cellulose form a gel in contact with the wound exudate instantly. Hydrofibres pick up liquids vertically so as not to irritate the wound edges or peri-wound skin. Occlusive wound coverings such as hydrocolloid dressings are impermeable for liquids and microorganisms. In diabetic foot wounds, occlusive dressings should be used cautiously because of the high risk of infection.



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