Diabetic Foot Syndrome

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Epidemiology

The most significant consequences of diabetic foot problems are ulcerations and amputations.

- Between 0.8 and 10 % of all people with diabetes mellitus suffer from a foot ulcer.
- The annual rate of new diabetic foot cases is between 2.2 and 5.9 %.
- Germany is in the upper range of European countries with its rate of over 60 000 amputations per year. Approximately 70 % of all amputations are performed on patients with diabetes mellitus.

Risk Factors

Foot lesions in diabetics are a result of a multi-factor process with the following causative factors.

- inappropriate footwear
- neuropathy (sensory, motor, autonomic)
- peripheral arterial disease (PAD)
- limited joint mobility (LJM)
- foot deformities
- psycho-social constellation.

Examination

The feet and footwear of all diabetics should be examined periodically (see **Table 1**). Each examination should cover the following points, as a minimum.

- Focused history (burning or stabbing pain, paraesthesia, feelings of numbness, absence of all sensation).
- Examination of both feet: skin status (integrity, turgor, formation of sweat), musculature, deformities, mobility, skin temperature, etc.
- Check sense of touch with a 10-g monofilament and/or vibration sensation with a Rydell-Seiffer tuning fork.
- Foot pulses (posterior tibial and dorsalis pedis arteries).

Sense of Touch

The filament is placed on the patient's skin (but not on calluses or scars) for one second and exerts 10 g of pressure. If this pressure is not perceived, the patient's sense of touch is already severely limited and its protective function has expired.

Foot Pulses

Whether the foot pulses can be found by palpation depends on the room temperature. If the pulses cannot be felt at the feet, then the pulses of the popliteal and femoral arteries should be examined. The fact that a foot pulse can be felt does not, in itself, exclude PAD! The German Diabetes Association's evidence based guideline "Diagnosis, Therapy, Progress Control and Prevention of Diabetic Foot Syndrome" recommends the following additional examinations.

- Measurement of arterial occlusion pressure over the dorsalis pedis and tibial posterior arteries.
- Determination of the ankle brachial index (ABI)

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PAOD

The customary symptoms of PAD (intermittent claudication, rest pain) are often absent because of concomitant neuropathy. The diagnostic algorithm (see **Fig. 2**) includes colour coded duplex sonography (CCDS), magnetic resonance angiography (MRA) of the pelvis and leg vessels, digital subtraction angiography (DSA) if intervention is contemplated or, less frequently, DSA of the pelvic and leg arteries. Adequate hydration is obligatory before and after an angiography in order to prevent contrast agent nephropathy. In cases of renal failure, an MRA should normally not be used. In these cases CO_2 can be used for contrast.

If a patient is diagnosed with a lesion in the context of diabetic foot syndrome (DFS), then this lesion should be classified in accordance with the extent of destroyed tissue and the presence of an infection and/or ischaemia (classification according to Wagner, Wagner-Armstrong classification, see **Table 2, 3**, **Fig. 1 a, b**).

Treatment

If the frequency of amputations is to be reduced by more than 50 %, then the following multi-disciplinary, multi-factor approach to treating diabetic foot ulcers will have to be adopted.

- Metabolic optimisation and treatment of underlying medical diseases.
- Infection control
- Debridement of devitalized tissue
- Effective relief from pressure
- Local wound treatment
- Therapy of vascular diseases
- Education of patients

Adjuvant therapies (e. g. hyperbaric oxygen therapy, stem cell therapy) should, at the present, continue to be reserved for patients at Wagner stage > 3 after all possibilities of revascularisation have been exhausted and with threat of extremity amputation.

Metabolism Optimisation and Treatment of Underlying Medical Diseases

Metabolism must be optimised if immunocompetence is to be maintained, haemorheology and thus microcirculation are to be improved and progression of pathological glycation is to be prevented. All secondary diseases which impact

- immunocompetence
- haemoperfusion, or
- tissue oxygenation

should be treated appropriately.

Infection

An infection is diagnosed clinically when there are systemic or local signs. The extent of infection in patients with diabetic foot syndrome is classified either as mild, moderate or severe or as life-threatening or not life threatening. (see **Table 7**). Admission to in-patient treatment is indicated in the case of severe infection and is possible with moderate infection. The following actions are to be taken: sufficient fluid intake, metabolic control, parenteral antibiotic therapy, drainage, and possibly further surgical measures. An infection with multiresistant germs worsens the prognosis.

Wound Debridement

Wound debridement is important for the effectiveness of other therapeutic interventions.

- Mechanical debridement: removal of necrotic layers in the wound bed and possibly from the wound borders. Debridement should be preceded by ensuring sufficient perfusion. Anaesthesia is usually not required due to the patient's neuropathy and strictly aseptic conditions are usually not necessary, due to due to preexistent microbial contamination.
- Biomechanical removal of unhealthy tissue: liquefaction of wound layers and necrotic tissue induced by proteases in maggot secretions (fly larvae).

Pressure Relief

Pressure can be relieved by total contact cast, therapeutic footwear, orthoses, use of crutches or wheelchair, or strict bed rest. Periodical callus removal is required for pressure relief.

Local Wound Treatment

Stage oriented wound treatment is generally recognised as appropriate for chronic, non-ischemic wounds. The dressing applied in an individual case should be selected on the basis of the quantity of exudate, the presence or absence of signs of infection and cost effectiveness criteria. The wound surface must be cleaned thoroughly at each change of dressing.

Therapy of Vascular Diseases

Revascularisation interventions, both operative and endoluminal, are indicated, more particularly when foot lesions do not heal or In the imminent danger of amputation. Percutaneous angioplasty is to be preferred when both revascularisation procedures are technically possible. One cannot expect a wound to heal when blood supply to the wound is insufficient.

Education

Training patients with the objective of preventing ulcers has proven to be an intervention that reduces the rates of ulcers and amputations in the short term. Repeat training of care givers also plays a significant role.

Amputation

When an amputation becomes necessary, its extent must be kept as small as possible so that weight-bearing areas are retained. Vascular work-up must be carried out before any amputation. A major amputation, (above the ankle) is never indicated as a primary intervention (see the Oppenheim Declaration).

Diabetic Neuropathic Osteo-Arthropathy (DNOAP) ("Charcot Foot")

DNOAP comes along with the destruction of single or multiple joints and/or bones (see Tables 5, 6 for classification by stage and localisation pattern). Neuropathy and (unnoticed) traumata are the causes of its development. The diagnosis in the acute phase of the disease ("acute Charcot foot") is crucial for the prognosis. The relevant method for diagnosing this disease is a plain x-ray of the foot in two planes together with clinical examination and a determination of the surface temperature in comparison to that of the other side. If the plain x-ray is negative, an MRI should be performed to recognise and differentiate the early stages of DNOAP (so-called "stage 0" according to Chantelau / Edmonds). The primary therapy consists of complete pressure relief and immobilisation.

Prevention

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Prevention is of decisive importance for avoiding ulcers and amputations. The preventive measures include:

- Identification of high risk patients (history of foot lesion or amputation and clinical examination including monofilament and pulse palpation).
- Periodic examination of feet and footwear.
- Appropriate footwear.
- Treatment of other pathological changes in the foot.
- podiatric management.
- Education of all persons involved
- Psychosocial care.

The interval between examinations should take account of the patient's risk profile. Mechanical factors play an essential role in the occurrence of diabetic foot ulcers. Repeated impacts of increased pressure and shear forces on the foot when the patient is walking lead to injuries. The most important cause of lesions is inappropriate footwear!

Organisation of Care

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The incidence of amputations is significantly decreased when care of the patient is shared by a multidisciplinary team of general practitioners, diabetologists, vascular specialists (vascular surgeons, angiologists and interventional radiologists), surgeons, diabetes ceducators, shoe makers and podiatrists.

Footwear

Most patients need adequate footwear both for outdoors and at home. The principles of proper footwear for patients with diabetes are based mostly on sufficient space and suitable insoles with even distribution of pressure, rather than on biomechanical, orthopedic correction of deformities. The shoes and in particular the insoles should be checked frequently for abrasion and replaced when necessary. The materials used to relieve pressure lose their effects over time. A practice oriented classification for prescribing footwear according to the the stage of the disease is available at www.ag-fuss-ddg.de (see ○ **Table 4**).

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Annex

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Table 1 Examination schedule for the foot, depending on the patient's risk profile.

Risk category	Risk profile	Examination
0	no sensory neuropathy, no PAD	annually
1	sensory neuropathy with or without deformity	every 3 – 6 mths.
2	PAD with or without sensory neuropathy	every 2 – 3 mths. (specialist)
3	previous ulcer or amputation.	every 1 – 2 mths. (specialist)

Table 2 Classification according to Wagner.

0	no lesion, possibly foot deformation or cellulitis
1	superficial ulceration
2	deep ulcer up to the joint capsule, tendons or bones
3	deep ulcer with abscess formation, osteomyelitis, infection of the joint capsule
4	limited necrosis in the forefoot or heel area
5	necrosis of the entire foot

Wagner 0: Periodic check of the feet.
Wagner 1 and Wagner 2: Focus on pressure relief and local wound care.
Wagner 3: Infection control. Usually, with systemic antibiotic therapy; small osteomyelitic foci are healed, larger foci generally have to be resected. X-ray findings usually lag behind the actual state of the bone. If the clinical findings improve, continuation of antibiotic therapy can also be guided by blood inflammation parameters. Normally, even small processes require an antibiotic therapy of 6 or more weeks duration.
Wagner 4, Wagner 5: Treatment is primarily focused on h keeping the amputation line as distal as possible and preventing proximal extension of infection. If the patient has PAD, an angiography should be performed before each amputation.

Table 3 Wagner-Armstrong Classification. Possibilities for describing diabetic foot syndrome (DFS) using the combined Wagner-Armstrong classification.

Wagner grade Armstrong stage	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 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

Foot Documentation Form of the "Diabetic Foot Working Group" of the German Diabetes Association.

Basic Data	**Facility:**
	Primary Doctor: .... Referring Doctor: .....

History:

Important long-term diagnoses:

....
....

Previous foot lesions (year): o none **Foot operations (year):** o none

....
....

antibiotic pre-treatment: o no o yes ..... MRSA ... o currently o in the past .....

Previous Shoe Care:

o no special shoes o protective shoes o custom made o soft cushion insole o DAF
o pressure relieving shoes
o shoe care is sufficient o shoe care is insufficient because .....

Angiology

PAD present o no o yes o critical ischaemia: o no o yes

Bypass (from ... to)	right	left
PTA	right	left

Pulse Status	**right**	**left**	**Angiography right**	**Angiography left**
femoral artery				
popliteal artery				
dorsalis Pedis artery				
posterior tibial artery				
claudication				

Doppler/Duplex Finding most recent Doppler/Duplex on.....

Occlusion pressure [mmHg]							**Blood flow profiles**	
	right			**left**			**right**	**left**
brachial artery								
popliteal artery								
dorsalis pedis artery								
tibial posterior art.								
fibular artery								
DI/cm (pole test) Dopplersound	o O	o 50	o 70	o O	o 50	o 70	other: (e.g. TcPO2)	

Chronic venous insufficiency	right	left
CVI Degree/PTS		

Fig. 1a Foot Documentation Form.

Foot Findings: (date): ..... o no lesions

Lesion since ..... o recurrent Ulcer-free time ..... months

Lesion: presumed cause .....

Localisation/Description/Size

right o photo	**left** o photo

Wound healing stage														
Extent Wagner-Armstrong		0	1	2	3	4	5		0	1	2	3	4	5
	A							A						
	B							B						
	C							C						
	D							D						
PEDIS	P	E	D	I	S			P	E	D	I	S		
DNOAP														
Sanders														
Levin														

Deformities o none

	right	**left**
Hallux valgus		
Claw toe/hammer toe/digitus superductus		
other		

Limited joint mobility o none

Hallux limitus		
Morbus Ledderhose		
other		

Neurology: PNP with sensitivity loss o no o yes

	right			left		
Vibration [x/8]	D1	Mall	Tib	D1	Mall	Tib
Achilles tendon reflex	none	weak	good	none	weak	good
10g Sem. Weinstein filament	MFK1	MFK 5	D1	MFK1	MFK5	D1
Neuropathy symptoms (score)						
other						

Diagnoses /:

.....
.....
.....
.....
.....

Date: ..... Signature: .....

Fig. 1b Foot Documentation Form (continued).

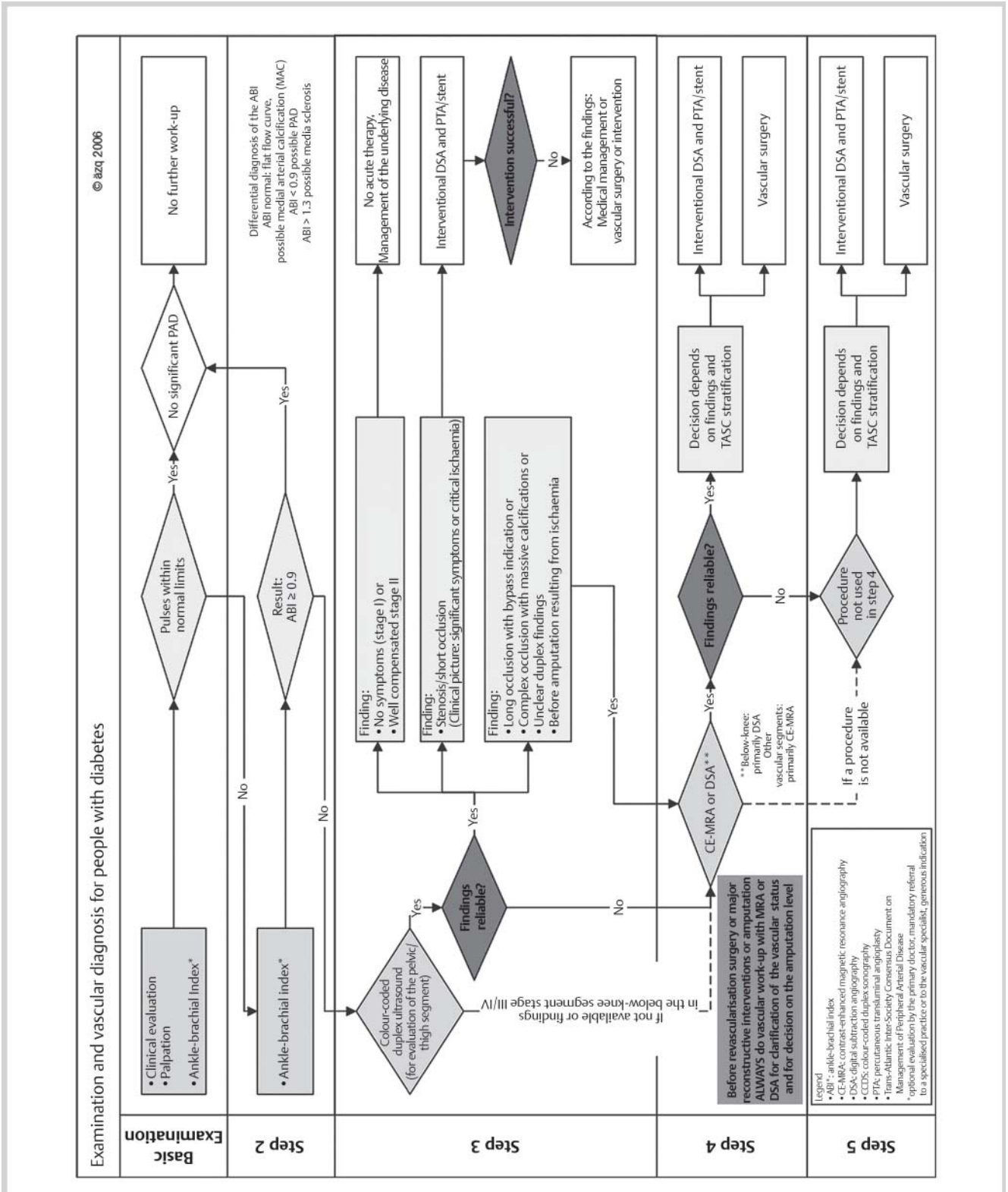

Fig. 2 Vascular diagnostics for diabetics.

Table 4 Provision of shoes and risk classes for diabetic foot syndrome and analogous neuro-angioarthropathies.

	Risk group	Explanation	Standard care
0	Diabetes mellitus without polyneuropathy or PAD	education and advice	mass-production shoes suitable for the feet
I	as with 0, but with foot deformity	increased risk of later occurrence of PNP/PAD	provision of orthopedic shoes on the basis of an orthopedic indication.
II	Diabetes mellitus with sensitivity loss from PNP/PAD	sensitivity loss proven by inability to perceive the Semmes-Weinstein monofilament.	Diabetes protective shoe with removable soft cushion insole, as applicable with orthopedic shoe device height care with diabetes adapted footbed (DAF), or orthopedic custom made shoes for foot proportions that cannot be fitted with a mass produced last/for foot deformity which leads to local increased pressure/for failed adequate pre-care/for orthopedic indications
III	status post plantar ulcer	significantly increase risk of recurrent ulcer as compared with level II.	Diabetes protective shoe, generally with DAF, as applicable with orthopedic shoe device height care with orthopedic custom made shoes for foot proportions that cannot be fitted with a mass produced last / for failed adequate pre-care / for orthopedic indications
IV	as with II, but with deformities or disproportions	cannot be cared for with mass produced lasts	orthopedic custom made shoes with DAF
V	DNOAP (LEVIN III)	orthoses generally with DNOAP type IV-V (Sanders) or with severe deviation from the vertical	orthopedic custom made shoes with diabetic adapted inlays that overlap the ankles, inner shoes, orthoses
VI	as with II, but with amputation of part of foot	at least a transmetarsal amputation, also as inner amputation	care as with IV plus prostheses
VII	acute lesion / florid DNOAP	always as temporary care	pressure relieving shoes, shoes for bandaged feet, interim shoes, orthoses, TCC possibly with DAF and orthopedic shoe device

Criteria for higher level care
a) contralateral major amputation
b) arthropathy hips / knee / upper ankle joint or joint implant with impaired function / contracture
c) amputation of big toe / resection metatarsal bone I
d) motor functional limitation / paresis of one or both legs
e) severe unsteadiness in walking and standing
f) extreme obesity (BMI ≥ 35)
g) renal failure that requires dialysis
h) job that requires much standing or walking
i) significant restriction of vision

– the criteria for higher level care must be documented so that they are verifiable and the underlying diagnoses must be stated on the physician's prescription.
– in individual cases the physician may prescribe simpler or more elaborate care than in the foregoing scheme, but must justify this with an explanation.
– the prescribed aids must be accepted by medical staff together with the patient. The supplier is responsible for showing the patient how to use them.

Are the prescribed components included in the delivery?
Is the fit correct?
Steadiness in standing, kicking and walking?
Is the foot properly protected and are the patient's functional limitations compensated?
Have the criteria for providing shoes for DFS been met?

Minimal criteria for providing shoes for DFS:
enough room for the toes in length and height; sufficient width; no seams that exert pressure; soft material over the parts of the movable foot that are threatened by pressure; toe cap (if any) does not exert pressure on the foot; mass produced cushion sole can be removed and reduces peak pressure in the ball area by 30 %; an orthopedic device can be attached

– the term "diabetic protective shoe" is to be used with the same meaning as similar terms such as "diabetic special shoe", "mass produced therapy shoe", "semi-orthopedic shoe", etc. When such a shoe is dispensed, its function in respect to statics and dynamics must be checked and, if necessary, optimised with an additional orthopedic device.
– verifiable documentation that the DAF actually produces local pressure relief can be obtained under dynamic conditions only with the help of pedobarographic measurement soles. Dynamic pedography is superior to static procedures (foot blueprints) for documenting the zones of increased pressure due to functional deformities.
– manual construction of an individual special last according to a plaster cast or comparable technology is required for correction or functional compensation of a high level foot deformity by means of custom made shoes. The current state of automation technology allows mass customisation only for slightly deformed feet.
– in cases of an acute lesion (ulcer or DNOAP that is still florid), total relief with an Allgöwer walking apparatus or a Thomas splint is required only in exceptional cases. With an ulcer, the focus is on pressure relief and redistribution, and with a DNOAP the focus is on eliminating foot joint movements.
– with cases in group III or higher, out-patient examinations are required at least once every 3 months as follow-up checks.

Draft presented by "Interdisciplinary Study Group Shoe Care for Diabetic Foot Syndrome" with participation by: Dr. Armin Koller, Orthopedic Specialist; Dr. Christsoph Metzger, Diabetologist; Michael Möller, OSM; Jürgen Stumpf, OSM; Dr. Karl Zink, Diabetologist.

Table 5 Progression of DNOAP according to Levin.

I	(acute stage): foot is red, swollen, hyperthermic (x-ray possibly still normal)
II	changes of bones or joints; fractures
III	foot deformity: flat foot, later rocker bottom foot through fractures and destruction of joints
IV	plantar foot lesion

Table 6 Localisation Pattern of DNOAP according to Sanders.

I	interphalangeal joints, metatarsophalangeal joints, metatarsals
II	tarsometatarsal joints
III	naviculocuneiform joints, talonavicular joint, calcaneocuboid joint
IV	ankle joints
V	calcaneus

Table 7 Clinical Classification of Foot Infections (modified in accordance with the International Consensus Working Group, 2003, and Infectious Diseases Society of America [IDSA] 2004).

Clinical manifestation of the infection	Infection severity	PEDIS Level
wound without pus discharge or signs of inflammation	not infected	1
presence of at least two inflammation signs (pus, redness, pressure pain, hyperthermia or induration), but each sign of inflammation extends at most 2 cm from the ulcer, infection is limited to the skin and surface subcutaneous tissue; no other local complications or systemic disease	mild	2
infection (as above) in a patient who is systemically healthy and metabolically stable, but has more than one of the following characteristics: inflammation signs extending more than 2 cm from the ulcer, lymphangitis, spreading under the superficial fascia, abscess in deep tissue, gangrene with muscle, tendon, joint or bones affected	moderate	3
infection in a patient with systemic infection signs or unstable circulation (e. g. fever, chills, tachycardia, hypotension, disorientation, vomiting, leucocytosis, acidosis, severe hyperglycaemia or azotaemia)	severe	4

Remark: The presence of critical ischaemia moves the degree of severity toward “severe” (in view of the prognosis), but this can attenuate the clinical signs of the infection.
PEDIS: Perfusion, Extent, Depth (tissue loss), Infection, Sensation.