

Appendix G:

PEDIS: Diabetic Foot Ulcer Classification System

In 2003, the International Working Group of the Diabetic Foot (IWGDF) introduced its classification system (PEDIS) for research purposes. On the basis of the scientific literature and expert opinion, five categories were identified:

- Perfusion
- Extent/Size
- Depth/Tissue Loss
- Infection
- Sensation

The 2011 International Consensus on the Diabetic Foot & Practical and Specific Guidelines on the Management and Prevention of the Diabetic Foot continues to support the use of the PEDIS system as a diabetic foot ulcer classification system. For each category within this system, a grading system is provided, describing the severity within each category.

Perfusion

GRADE 1 No symptoms or signs of PAD in the affected foot, in combination with:

- Palpable dorsal pedal and posterior tibial artery **or**
- Ankle Brachial Index 0.9 to 1.10 **or**
- Toe Brachial Index > 0.6 **or**
- Transcutaneous oxygen pressure (TcPo₂) > 60 mmHg

GRADE 2 Symptoms or signs of PAD, but not of critical limb ischemia (CLI)

- Presence of intermittent claudication*, as defined in the document of the International Consensus on the Diabetic Foot **or**
- Ankle Brachial Index < 0.9, but with ankle pressure > 50 mmHg **or**
- Toe Brachial Index < 0.6, but systolic toe blood pressure > 30 mmHg **or**
- TcPo₂ 30 - 60 mmHg **or**
- Other abnormalities on non-invasive testing, compatible with PAD (but not with CLI).

Note: If tests other than ankle or toe pressure or TcPo₂ are performed, they should be specified in each study.

GRADE 3 Critical limb ischemia, as defined by:

- Systolic ankle blood pressure < 50 mmHg **or**
- Systolic toe blood pressure < 30 mmHg **or**
- TcPo₂ < 30 mmHg

* In case of claudication, additional non-invasive assessment should be performed

Extent/Size

Wound size (measured in square centimetres) should be determined after debridement, if possible. The outer border of the ulcer should be measured from the intact skin surrounding the ulcer. If wound healing is one of the end-points in a study, tracing of the wound, planimetry or the grid technique should be used for sequential measurements of the wound area. If, on the other hand, wound size is measured only at the time of recruitment into a study and intact skin is the primary end-point, the surface area can also be estimated by multiplying the largest diameter by the second largest diameter measured perpendicular to the first diameter. However, this technique is clearly less precise. The frequency distribution of the size of the ulcers should be reported in each study as quartiles.

Depth/Tissue Loss

Depth is difficult to determine and relative; an ulcer which is only a few millimeters deep on a toe can penetrate into bone or a joint, but, in other regions, ulcers can be several centimeters deep without involvement of deeper structures. Therefore, ulcers are divided into lesions confined to the skin and those deeper than the skin. Even if an ulcer does not seem to penetrate below the skin, clinical infection in subcutaneous tissues (e.g., an abscess or osteomyelitis) means it is a “deep” ulcer. The extent of tissue loss should be evaluated after initial debridement, but this should be performed judiciously when critical limb ischemia (Grade 3) is suspected.

GRADE 1	Superficial full thickness ulcer, not penetrating any structure deeper than the dermis.
GRADE 2	Deep ulcer, penetrating below the dermis to subcutaneous structures, involving fascia, muscle, or tendon.
GRADE 3	All subsequent layers of the foot involved, including bone and/or joint (exposed bone, probing to bone).

Infection

Infection of a diabetic foot ulcer is defined as invasion and multiplication of microorganisms in body tissues associated with tissue destruction or a host inflammatory response. Infection is defined clinically, by the symptoms and signs of inflammation as described below, regardless of the results of any wound culture.

Studies on accuracy and validity of different tests for diagnosing infection in diabetic foot disease are scarce. Therefore, the scheme described below is based mainly on expert opinion.

In grading infection, three parameters, in particular, are relevant to clinical management and possibly to outcome: the involvement of skin only; the involvement of deeper structures and the systemic inflammatory response of the patient. In daily practise the term a “limb-threatening” infection is also frequently used. However, this category is very difficult to define and overlaps with the other categories.

GRADE 1	No symptoms or signs of infection
GRADE 2	<p>Infection involving the skin and the subcutaneous tissue only (without involvement of deeper tissues and without systemic signs as described below). At least 2 of the following items are present:</p> <ul style="list-style-type: none"> ■ local swelling or induration; ■ erythema > 0.5 to 2 cm around the ulcer; ■ local tenderness or pain; ■ local warmth; and/or ■ purulent discharge (thick, opaque to white or sanguineous secretion). <p>Other causes of an inflammatory response of the skin should be excluded (e.g., trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis).</p>
GRADE 3	<p>Erythema > 2 cm plus one of the items described above (swelling, tenderness, warmth, discharge) or</p> <p>Infection involving structures deeper than skin and subcutaneous tissues such as abscess, osteomyelitis, septic arthritis, fasciitis.</p> <p>No systemic inflammatory response signs, as described below.</p>
GRADE 4	<p>Any foot infection with the following signs of a systemic inflammatory response syndrome (SIRS). This response is manifested by two or more of the following conditions:</p> <ul style="list-style-type: none"> ■ Temperature > 38 or < 36 Celsius; ■ Heart rate > 90 beats/min; ■ Respiratory rate > 20 breaths/min; ■ PaCO₂ < 32 mmHg; ■ White blood cell count > 12.000 or < 4.000/cu mm; and/or ■ 10% immature (band) forms.

Sensation

The system categorizes patients as having present or absent protective sensation in the affected foot. The system does not categorise patients as having (diabetic) polyneuropathy, and additional information is needed for this diagnosis. Moreover, it does not provide information on the cause of the loss of protective sensation, nor is the severity of the sensory loss graded. Both pressure and vibration sensation should be determined in each patient.

GRADE 1	No loss of protective sensation on the affected foot detected, defined as the presence of sensory modalities described below.
GRADE 2	<p>Loss of protective sensation on the affected foot is defined as the absence of perception of the one of the following tests in the affected foot:</p> <ul style="list-style-type: none"> ■ Absent pressure sensation, determined with a 10 gram Monofilament, on 2 out of 3 sites on the plantar side of the foot, as described in the International Consensus on the Diabetic Foot; and/or ■ Absent vibration sensation, (determined with a 128 Hz tuning fork) or vibration threshold > 25 V, (using semi-quantitative techniques), both tested on the hallux.

Note. From “Classification of diabetic foot ulcers for research purposes,” by N.C. Schaper, 2004, *Diabetes/Metabolism Research and Reviews*, 20(Suppl 1), S90-S95. Reprinted with permission.