

**Official title of the study:** Abnormal Plantar Pressure in patients with Diabetes.

**NCT number:** 03426566

**Date:** 01 January 2014

**1. Recruitment Details:**

Recruitment period: between October 2009 and December 2010

Type of location: All of the documents were obtained from the Diabetic Foot Centre (DFC) in Wroclaw, Poland, where the patients had consultations, covered a period of fifteen months of work.

**Pre-assignment Details:**

Patients without previous ulcerations or foot surgery were evaluated- if there were any doubts, the patient's results were not taken into consideration.

**Arm/Group Information:**

**Arm/Group Title:**

Non-ulcer patients with diabetes mellitus.

**Arm/Group Description:**

Patients with diabetes mellitus but without active or past foot ulcer or surgical procedure within the feet.

**Type of Units Assigned:**

Not applicable

**Period(s):**

All medical records were analyzed between September 2012 and January 2014.

**Started:**

974 medical records

**Completed:**

974 medical records

**2. Baseline Characteristics:**

**Arm/Group Information**

Table 1. Baseline characteristics of the study population: sex, age, BMI

NT	Age (years) mean $\pm$ SD (range)	BMI (kg/m <sup>2</sup> ) mean $\pm$ SD (range)
974	64.6 $\pm$ 11.15 (21-90)	29.9 $\pm$ 5.22 (18.5-66.7)
451♂	63.8 $\pm$ 10.9 (24-90)	29.44 $\pm$ 4.74 (18.5-46.2)
523♀	65.3 $\pm$ 11.33 (21-88)	30.4 $\pm$ 5.56 (19-66.7)

NT- total number of patients    SD-standard deviation

**Baseline Measure Information**

**Baseline Measure Title**

- **Age:**

**Age, Continuous:** mean with SD (Table 1)

**Age, Categorical:** \* $\leq$ 40 years

\* 41-50 years

\* 51-60 years

\* 61-70 years

\* 71-80 years

\* 81-90 years

- **Sex:** Female (♀), Male (♂) (Table 1)
- **BMI :** mean with SD (Table 1)

### **Baseline Measure Description**

**Age-** was calculated based on patients ID (identification) number (in Poland each ID number contains date of birth).

**Sex:** based on information from medical records

**BMI:** BMI was calculated based on the height and weight assessed during the visit and recorded in the medical records. BMI was defined as the body mass in kilograms divided by the square of the body height in meters, and expressed in units of  $\text{kg}/\text{m}^2$

### **Measure Type**

- Count of participants
- Mean

## **Measure Dispersion**

- Standard Deviation
- range

## **Number of Baseline Participants**

974 participants: women: 523, men: 451;

Age categories: ≤40: 36;

41-50: 51;

51-60: 233;

61-70: 333;

71-80: 269;

81-90: 52

### **3. Outcome Measures**

#### **Primary Outcome Measure**

**Outcome Measure Title:** Abnormal Plantar Pressure Distribution (APD)

**Outcome Measure Description:** APDs were analysed for the forefoot (P1- 25% of the foot length) and mid-foot (P3- 28% of the foot length), with a separate evaluation for the lateral (P2) part of the mid-foot (the edge of the foot). The load of the hallux (20% of foot length) and rearfoot (27% of the foot length) was not analysed. The mentioned percentage for the appropriate lengths from the foot

print was calculated from the total length measured from the heel end to the furthest point (1st toe or other toe). We used colour intensity analysis to demonstrate the presence of the maximum pressure (peak pressure) represented by the hottest colour – the red one. If necessary, the patient repeated the test until a correct impression of the foot (symmetric with the corresponding location of the centre of the mass). For the heel the red colour does not constitute pathology, because this colour always indicates a site of greatest pressure (typically presented within the heel). The heel load evaluation is therefore only useful if it includes absolute pressure value assessment.

### **Outcome Measure Time Frame**

The APD rating for each patient was one-off and took place during one visit in the Centre. Data for all participants come from 15 months of observation.

### **Arm/Group Information**

#### **Arm/Group Title:**

1. Patients with no APD.
2. Patients with APD.

#### **Arm/Group Description:**

1. Patients with no APD- participants with correct load rates based on the print (three main load points on the both feet: central part of the heel; the 1st and 4th - 5th metatarsal heads)
2. Patients with APD- participants with at least one abnormal load point, within forefoot and/or mid-foot and/or lateral edge of the foot, on at least one foot

### **Secondary Outcome Measure**

**Outcome Measure Title:** Neuropathy

**Outcome Measure Description:** Parameters for symmetric, peripheral, sensory-motor neuropathy was assessed. The motor component of the neuropathy causes muscle atrophy within the feet with subsequent abnormal distribution of the plantar pressure (invisible in standard physical examination) then visible feet deformity and calluses. Information about visible deformities and calluses were derived from physical examination. Deformities included hammer- or claw-toes, hallux valgus, visible flat feet, or “other visible deformities “. The calluses were defined as thick, hardened layers of the skin. The sensory component of the neuropathy was assessed with a questions and clinical evaluation. A skilled nurse asked patients about stinging, numbness, tingling, or burning of the foot for the questionnaire items. Ten-gram monofilament and tuning fork (128 MHz) tests were administered. Monofilament was applied in 10 locations on the sole (calluses were avoided) and one on the dorsal part of the foot for checking the loss of protective sensation. A positive monofilament test was considered to be the lack of sensation of tightness in at least 6 of 11 tested sites. The tuning fork was applied for vibration detection to both ankles, the first metatarsophalangeal joint, and the anterior aspect of the shin bone sites. A positive vibration test was considered to be no detection of vibration in three of four test sites.

The condition required for the occurrence of these disorders (MN-motor and/or PSSN- peripheral, symmetric, sensory neuropathy) was symmetry.

### **Outcome Measure Time Frame**

The neuropathy assessment for each patient was one-off and took place during one visit in the Centre. Data for all participants come from 15 months of observation.

### **Arm/Group Information**

**Arm/Group Title:**

1. PSSN negative
2. PSSN positive
3. MN negative
4. MN positive

**Arm/Group Description:**

1. Patients without sensory component of the neuropathy- participants with asymmetrical disturbances and/or less than two positive test results and without minimum one typical neuropathy symptom as well as patients with less than two positive test results and with typical neuropathy symptom.
2. Patients with sensory component of the neuropathy- participants with two positive test results and typical symptoms of the neuropathy or participants with two positive test results without typical neuropathy symptom. The condition required for the occurrence of these disorders was symmetry.
3. Patients without motor component of the neuropathy- participants without visible feet deformity and/or calluses.
4. Patients with motor component of the neuropathy- participants with visible feet deformity and/or calluses. The condition required for the occurrence of these disorders was symmetry.

**Outcome Measure Title:** Body Mass Index

**Outcome Measure Description:** BMI was defined as the body mass in kilograms divided by the square of the body height in meters, and expressed in units of  $\text{kg}/\text{m}^2$

### **Outcome Measure Time Frame**

The BMI was calculated for each patient ones during one visit in the Centre. Data for all participants comes from 15 months of observation.

### **Arm/Group Information**

#### **Arm/Group Title:**

1. BMI  $\geq 35$  kg/m<sup>2</sup>
2. BMI  $< 35$  kg/m<sup>2</sup>

#### **Arm/Group Description:**

1. Patients with BMI  $\geq 35$  kg/m<sup>2</sup>
2. Patients with BMI  $< 35$  kg/m<sup>2</sup>

### **Analysis Population Information**

**Primary Outcome Measure: Outcome Measure Title:** Abnormal Plantar Pressure Distribution (APD); **Overall Number of Participants Analyzed** : 974; 1. Patients with no APD: 80; 2. Patients with APD: 894

**Secondary Outcome Measure: Outcome Measure Title:** Neuropathy; **Overall Number of**

**Participants Analyzed:** 974; 1. PSSN negative: 907 2. PSSN positive: 67

3. MN negative: calluses: 645; foot deformity: 798

4. MN positive: calluses: 329; foot deformity: 176

**Secondary Outcome Measure: Outcome Measure Title: BMI: Overall Number of**

**Participants Analyzed: 974:** 1. Patients with BMI  $\geq 35$  kg/m<sup>2</sup> : 153; 2. Patients with BMI <35 kg/m<sup>2</sup> : 821

**Outcome Measure Data Table**

**Primary Outcome Measure: Outcome Measure Title: Abnormal Plantar Pressure Distribution (APD): Outcome Measure Data Table**

**Measure Type:** count of participants

Table 1 APD in: forefoot, lateral part of the foot, mid-foot.

NT	Patients with at least one APD regardless of the location	APD within forefoot	APD within lateral part of the foot	APD within mid-foot
♂ n=451	408	380	78	5
♀ n=523	486	426	138	21
974	894	806	216	26

NT- total number of patients

APD- abnormal plantar pressure distribution

**Secondary Outcome Measure: Outcome Measure Title: Neuropathy: PSSN and MN Outcome Measure Data Table**

**Measure Type:** count of participants

Table 2. PSSN and MN (calluses and visible foot deformities) in patients with and without APD.

NT	Patients with Abnormal Plantar pressure Distribution	Patients without Abnormal Plantar pressure Distribution	NT
Patients without Peripheral Symmetric Sensory Neuropathy	833	74	907
Patients with Peripheral Symmetric Sensory Neuropathy	61	6	67
Patients without Calluses	588	57	645
Patients with Calluses	306	23	329
Patients without Foot Deformity	728	70	798
Patients with Foot Deformity	166	10	176

NT- total number of patients

APD- abnormal plantar pressure distribution

PSSN- peripheral, symmetric, sensory foot neuropathy

**Secondary Outcome Measure: Outcome Measure Title: BMI. Outcome Measure Data Table**

**Measure Type:** count of participants

Table 3. BMI <35 and BMI ≥35 in patients with and without APD within: forefoot, lateral part of the foot, mid-foot.

NT	Patients without APD within the forefoot	Patients with APD within the forefoot	Patients without APD within lateral part of the foot	Patients with APD within lateral part of the foot	Patients without APD within the mid-foot	Patients with APD within the mid-foot
BMI						
<35	128	693	665	156	808	13
821						
BMI						
≥35	40	113	93	60	140	13
153						

BMI- body mass index; NT- total number of patients

APD- abnormal plantar pressure distribution

### Statistical Analyses

#### Statistical Analysis Overview

The Statistica 9 PL (StatSoft) software package was used for statistical analysis.

The Kolmogorowa - Smirnowa test was used in the distribution analysis.

According to the result of the analysis the parametric, T-test or nonparametric, U Mann-Whitney test was used in further calculations.

The Chi-square test was used to determine the association between two categorical variables.

A *P* value <0.05 was considered statistically significant.

Data are presented as means ( $\pm$ S.D.).

#### **4.Adverse Event Information**

Not applicable- observational, retrospective study with medical-records analysis.

#### **5.Limitations and Caveats**

1. It was not possible to carry out this analysis for the different types and duration of DM due to the lack of complete data in the analysed medical records coming from the Centre. The disease duration may be connected with higher peak pressure within the feet due to the plantar contact area narrowing (showed previously in dynamic evaluation).
2. The evaluation of the neuropathy in the Diabetic Foot Centre was based on local recommendation and not on e.g. Michigan Neuropathy Screening Instrument (MNSI). However, as a research tool in the mentioned Centre were used: foot inspection, vibration sensation, monofilament testing, and questionnaire for symptoms. This tool was similar to the MNSI.
3. The semi-quantitative analysis of the pressure map (colors), the retrospective nature of the study and the nature of the Center (although the authors involved patients from only one center of a large urban area, the available data seem to be representative of the entire diabetic population).

#### **6.Certain Agreements**

Yes-The principal investigator is an employee of the sponsor.

There is no results disclosure restriction.

**7.Results Point of Contact**

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