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Efficacy measures associated to a plantar pressure based classification system in diabetic foot medicine

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ABSTRACT

Aims: The concept of 'classification' has, similar to many other diseases, been found to be fundamental in the field of diabetic medicine. In the current study, we aimed at determining efficacy measures of a recently published plantar pressure based classification system.
Methods: Technical efficacy of the classification system was investigated by applying a high resolution, pixel-level analysis on the normalized plantar pressure pedobarographic fields of the original experimental dataset consisting of 97 patients with diabetes and 33 persons without diabetes. Clinical efficacy was assessed by considering the occurence of foot ulcers at the plantar aspect of the forefoot in this dataset. Classification efficacy was assessed by determining the classification recognition rate as well as its sensitivity and specificity using cross-validation subsets of the experimental dataset together with a novel cohort of 12 patients with diabetes.
Results: Pixel-level comparison of the four groups associated to the classification system highlighted distinct regional differences. Retrospective analysis showed the occurence of eleven foot ulcers in the experimental dataset since their gait analysis. Eight out of the eleven ulcers developed in a region of the foot which had the highest forces.
Overall classification recognition rate exceeded 90% for all cross-validation subsets. Sensitivity and specificity of the four groups associated to the classification system exceeded respectively the 0.7 and 0.8 level in all cross-validation subsets.
Conclusions: The results of the current study support the use of the novel plantar pressure based classification system in diabetic foot medicine. It may particularly serve in communication, diagnosis and clinical decision making.

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1. Introduction

Diabetes mellitus (DM) is one of the most common non-communicable diseases, with an estimated global prevalence of 9.9% or 552 million adults affected in 2030 [1]. Approximately 11% of total healthcare expenditure in adults between 20 and 79 years has been attributed to the disease in 2011 (465 billion US dollars).

The concept of 'classification' has, similar to many other diseases, been found to be fundamental in the field of diabetic medicine, especially since its pathogenesis has been understood experimentally [2]. Classifying according to the type of glycaemia disorder is common practice nowadays, even if a single patient cannot always be assigned to a single class [3]. Together with the increasing insight about the secondary complications associated to hyperglycaemia induced damage [4], the scientific community has felt the urge to develop more appropriate classification systems to specifically assist in diagnosis, clinical decision-making and communication. A typical example of the latter are the plethora of classification systems described in the field of the foot in diabetes, the latter being a syndrome covering devastating foot complications associated to DM [5]. Ulcer severity classification systems [6,7] and ulcer risk classification systems [8,9] are considered as cornerstones of good clinical management in foot care nowadays as they have shown to discriminate patients with an increasing likelihood of foot ulcer and/or amputation [10,11]. The clinical success of the aforementioned classification systems has also triggered a number of research groups in establishing a classification system based on gait features of patients with diabetes [12–15]. The common objective of these research groups is not only based on intuition or curiosity (classification is a primitive conceptual activity of human beings [16]), but mainly on evidence from the literature that risk of foot ulceration can be increased by foot biomechanics and gait dysfunction [17]. The consideration of plantar pressure measurements is in this perspective especially appealing, as it is the most affordable equipment allowing the quantification of plantar skin loading during walking [18]. To our knowledge, three manuscipts have dealed with the classification of plantar pressure measurements in patients with DM. Giacomozzi and Martelli [13] established a classification system based on the shape and amplitude of the time curve of the instantaneous maximum pressure. The application of Kmeans clustering on the magnitude and shape of peak pressure curves resulted in the establishment of a 'shape-based classification' system. Additionaly, a 'functional classification' system was described by differentiating peak pressure curves based on the single or simultaneous occurrence of limited joint mobility, muscular weakness and increased peak pressure. Bennets et al. [14] discriminated up to 10 barefoot plantar pressure patterns in a cohort of 438 patients with diabetes. Their classification system was obtained following the application of kmeans cluster algorithm on the regional peak plantar pressures of seven regions of interest. More recently, Deschamps et al. [15] published a classification system based on relative regional impulses in the forefoot of persons with and without diabetes. Four distinct pressure clusters (groups/patterns) were described and first signs of face validity were recognized as matching with the history of plantar foot ulcer localization was qualitatively reported. However, before this classification system can be used with sufficient confidence and according to the principles of evidence based practice, validation with respect to clinical and research practice should be obtained. In medicine, the latter is typically addressed within the framework of 'efficacy research' [19]. Typical measures of analysis associated to this research have been categorized into six levels by Fryback and Thornbury [19]. The first objective of the current study was to assess the technical efficacy of the classification system published by Deschamps et al. [15]. We also aimed at determining the clinical efficacy of this classification system, by analyzing the classification recognition rate, the sensitivity, the specificity as well as the usefulness of the the system in guiding pressure distribution strategies.

2. Methods

2.1. Ethics statement

The University Hosptials of Leuven Medical Ethics Committee approved the study and all study participants gave written informed consent.

2.2. Study population

2.2.1. Experimental dataset (Exp_DS)

Adults diagnosed with Type 1 and Type 2 diabetes, according to WHO criteria, associated to the classification study of Deschamps et al. [15] were considered in the current study. In the current study, we will use the acronym 'BDF_PPCS' (Belgian Diabetes Foot Plantar Pressure Classification System) when referring to this classification system.

This dataset consisted of 97 patients with diabetes who were recruited in two Belgian Diabetes Foot Centres (Flanders) (University Hospitals Leuven and Onze Lieve-Vrouw Ziekenhuis Aalst). Inclusion criteria for the subjects with diabetes were: age between 45–70 years, walking without walking aids, BMI between 20 kg/m^2 and 40 kg/m^2, oedema score < 2 [20], no active foot ulcer or amputation, no history of orthopaedic lower limb surgery and no Charcot neuroarthropathy. Following recruitment in each clinic, a study specific medical record and standard physical screening were completed.

In addition to this diabetes cohort, also a control cohort of 33 persons without diabetes associated to the BDF_PPCS study were considered. For the purpose of the current study, both aforementioned cohorts will be considered as 'experimental dataset' (Exp_Ds, N = 260 feet). More information on this Exp_DS can be found in the BDF_PPCS study [15].

2.2.2. Novel dataset (Novel_DS)

Twelve patients with diabetes fullfilling the same inclusion criteria as the abovementioned Exp_DS were recuited in a third Belgian Diabetes Foot Centre (Ziekenhuis Oost-Limburg). This diabetes foot centre is, similar to the two aforementioned diabetes foot centres, also involved 'Initiative for Quality Promotion and Epidemiology at Multidisciplinary Diabetes Foot Clinics' (IQED-Foot) organised by the The Scientific Institute for Public Health (Belgium). Different members of this diabetes foot centre participated actively in the design of the BDF_PPCS study [15] in order to guarantee the adequate execution of this multi-center study. For the purpose of the current study, the dataset associated to the Ziekenhuis Oost-Limburg diabetes foot center will be called novel dataset (Novel_Ds, N = 24 feet). Demographic and medical data of this Novel_DS are reported in Table 1.

2.3. Instrumention/gait analysis protocol

Gait analysis of the patients with diabetes associated to the Novel_DS was performed within the Laboratory for Clinical Movement Analysis of the University Hospitals Leuven. The instrumentation and gait analysis protocol from the BDF_PPCS study was used to analyze the walking pattern of the Novel_DS. Briefly, subjects walked barefoot at their preferred walking speed using the midgait protocol. Plantar pressure data were collected at 200 Hz using a footscan 0.5 m plate (dimensions 0.5 m $\times$ 0.4 m, 4096 resistive sensors, spatial resolution 2.8 sensors per cm^2,