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The proprioceptive insole: A therapeutic aid for the diabetic patient in prevention?

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ABSTRACT

The diabetic foot represents one of the most common complications among patients with type 2 diabetes mellitus. Prevention of the diabetic foot is therefore essential both to ensure the patient a better quality of life and to reduce the costs borne by the NHS and this requires a multidisciplinary approach. It is important to underline that the major complications of the diabetic foot are due to biomechanical, vascular and neuropathic alterations. Diabetic patients are less likely to perform physical exercises and tend to walk less, adopting compensatory strategies based on the type of terrain they find. They walk slower, tend to take shorter steps with a wider base of support, have limited knee and ankle mobility. It is very important to study the biomechanics and hyperload points in order to assess the risk of ulceration. In this study we decided to treat the postural alterations of diabetic patients not suffering from neuropathy with the use of proprioceptive insoles by analysing the degrees of perturbation of postural balance using a stabilometric platform. This work intends to evaluate the objective possibility of considering posturology in diabetology as an instrument discipline, to guarantee the patient less risk of ulceration through a correct postural structure and a possible postural reprogramming.

Keywords: Biomechanics; Diabetes; Proprioception; Diabetic foot; Insole; Posturology.

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INTRODUCTION

Diabetes Mellitus is a chronic disease caused by genetic and environmental factors, characterized by inappropriately elevated blood glucose levels, linked to an insufficient production and/or efficacy of the peptide hormone insulin (Kharroubi and Darwish, 2015).

Among the complications related to the Diabetes Mellitus, the diabetic foot represents one of the most common, with the possibility of losing a limb due to its degeneration representing almost 70% of all amputations worldwide (Francia et al., 2014). The major complications of the diabetic foot are due to biomechanical, vascular, and neuropathic adaptations (Ahmmed and Mackenzie, 2003). The term "*diabetic foot*" also means an alteration of the musculoskeletal and skin systems, which will result in the alteration of the breech structure. An early diagnosis and timely management of the disease represent a valid preventive procedure. Prevention practices, based on multidisciplinary approaches, are therefore fundamental both, to ensure the patient a better quality of life, and to reduce the costs borne by the National Health Systems.

The most frequent and most interesting form of neuropathy associated with the diabetic foot is the distal symmetrical polyneuropathy, defined as damage to the peripheral, somatic, or vegetative nervous system attributable solely to diabetes (Bansal, Kalita, and Misra, 2006). Has been described how diabetic patients tend to use different feet positions due to redistribution of pressure, deformities, and callus formation and to walk less and less, adopting compensation strategies (Ahmmed and Mackenzie, 2003). They walk more slowly, tend to take shorter steps with a wider base of support, have limited knee and ankle mobility, as already stated in the study by Oh-Yun Kwon et al. (2003), who observed a reduction of the ROM of diabetic subjects compared to control group.

The motor deficit initially manifests itself with loss of tone and progressive atrophy of the extrinsic muscles of the foot, followed by changes in the relationship between the extensor and flexor muscles of the fingers which, consequently, leads to dorsal hyperextension of the metatarsophalangeal joint and accentuation of the plantar arch. The toes are deformed with a hammer-like or claw-like appearance, the foot becomes hollow, and the big toe becomes valgus. Although from the point of view of the harmful risk, a pronated feet showed a higher risk of ulceration than supinated feet (Molines-Barroso et al., 2016). These deformations may further lead to an alteration of the distribution of plantar loads with the development of areas of hyperload, where plantar ulceration may appear. To all this must be added the development of plantar hyperkeratosis determined by the synergistic action of the reduction of proprioceptive sensitivity and anatomical and functional alterations (Molines-Barroso et al., 2016). These alterations of different nature increase insecurity in walking while decreasing stability in standing position, these precursors of the risk of falling.

It is well established the importance of the foot as a sensory organ, displaying almost 2700 specific receptors for different sensations that are the basis of particular postural reflexes (Ivanenko and Gurfinkel, 2018; Patti et al., 2017; Patti et al., 2018; Battaglia et al., 2020). Consequently, the correct function of the foot and its integration into the balance system is of significant importance.

In 2010 Wrobel and Najafi systematically reviewed main causes of alterations in the gait pattern and highlighted the following aspects as the main altering factors: a) increased stiffness and decreased thickness of the skin; b) depletion and displacement of plantar fat pads; c) decreased ROM; d) decrease in muscle mass with related atrophy; e) depletion of bone density; f) diffuse tendon thickening. All these factors have

been recognized as capable to interact and impact significantly on posture and biomechanics of the diabetic subject, impairing gait, stability and potentially contributing to reducing the quality of life.

This was further confirmed by a recent review published in 2016 by Hazari et al., in which the authors highlighted a significant aspect of biomechanical alterations in the diabetic foot and also the presence of stiffness in the joints of the foot and lower limb in the diabetic patient.

The acquisition and evaluation of kinematic and postural data is thus of fundamental importance for characterizing the diabetic patient, evaluating, segment by segment, all the alterations and integrating them, if possible, with the baropodometric data. However, few studies covered such aspect, and in particular, focusing on posture alteration evaluation as a preventive screening in diabetic patients.

METHODS

Participants

Twenty diabetic subjects (12 male, 6 females, 59.3 ± 8.8 years; 66.2 ± 8.2 kg; 165.4 ± 8.7 cm) voluntary accepted to participate after signing the informed consent forms.

Study design

The study protocol provided a first qualitative evaluation through the assessment of the general conditions of the foot, of the skin and through a segmental functional evaluation. The qualitative evaluation was followed by a quantitative instrumental analysis involving a computerized stabilometry assessment performed in the Romberg standardized breech position (Scoppa et al., 2017). The testing procedures were followed by the prescription of a training protocol performed under the supervision of a physiotherapist and by the preparation of a tailored proprioceptive insole. The subjects performed the training protocol and wore the proprioceptive insole for a period of two months. After the two-months intervention the subjects repeated all the testing procedures previously described. All the tests were carried out and supervised by expert physiotherapists, podiatrists, medical doctors and strength and conditioning staff. The protocol and procedures of the present study were designed in accordance with the Declaration of Helsinki (2008), with the Fortaleza update (2013).

Statistical analysis

All data in text, tables, figures are represented as mean \pm standard deviation (SD), means with 95% confidence interval (95% CI) where specified. Tests of normal distribution was determined by the Shapiro-Wilk test. Differences in pre to post variations were tested by the paired t-test. Cohen's *d* was additionally calculated, and the following criteria were adopted to interpret the effect size of the measured variables: < 0.09, trivial; 0.10 to 0.29, small; 0.30 to 0.49, moderate; 0.50-0.69, large; 0.70-0.89 very large; and > 0.90, nearly perfect (Hopkins, Marshall, Batterham, & Hanin, 2009). The level of significance of 5% (p < .05) was adopted in all analyses. All data analyses were carried out using SPSS version 21.0 (IBM Corporation, Armond, NY) and GraphPad Prism version 7.0 (GraphPad Software, San Diego, CA, USA).

RESULTS

Table 1. Descriptive statistics of pre- to post- variations in stabilometry measures.

	Pre	Post
Ellipse surface (mm ²)	198.1 ± 92.71	137.9 ± 75.7
CoPx (mm)	20.06 ± 9.16	15.49 ± 6.81
CoPy (mm)	19.91 ± 6.66	14.47 ± 6.13

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Descriptive statistics (mean \pm SD) are represented in Table 1. The qualitative analysis revealed that 65% of the study participants displayed a hollow foot posture, while 35% a flat foot posture.

The Shapiro-Wilk normality test revealed normal distributed data set for all the measured parameters. Thus, from the paired t-test performed on pre to post stabilometry test data emerged significant differences for the ellipse surface (mm²) [t(19) = 5.896; p < .0001; mean difference (95%CI) = -60.19 (-81.55 to -38.82); d = 0.71; *interpretation*: very large], for CoPx [t(19) = 3.539; p = .0022, mean difference (95%CI) = -4.57 (-7.27 to -1.86); d = 0.56; *interpretation*: large], and for the CoPy [t(19) = 6.897; p < .0001; mean difference (95%CI) = -5.43 (-7.08 to -3.78); d = 0.85; *interpretation*: very large] (Figure 1).



Note: **** *indicates p* < .0001; ** *indicates p* > .01.

Figure 1. Results of the paired t-test between pre and post intervention considering the stabilometry measures (from top to bottom: ellipse surface, CoPx, CoPy).

DISCUSSION

The present study aimed to screen and treat the postural alterations of non-neuropathic diabetic patients with the use of proprioceptive insoles and by analysing the degrees of postural balance decompensation using a stabilometric platform.

The main findings of our investigations depicted a positive and significant impact of the joint and multidisciplinary approach to prevent possible complications linked to the diabetic foot. In particular, all the stabilometric markers improved after the intervention.

The screening procedures produced results similar to previous observations (Mehdikhani et al., 2014) as well we observed how this protocol had a good impact on patients from all points of view analysed, integrating motor activity with clinical care, and confirming the positive impact of the exercise therapy in diabetic patients (Francia et al., 2014).

We believe that today the multidisciplinary approach to the diabetic patient is increasingly important, where every healthcare figure can bring their know-how to the care project that will therefore be tailored to the patient. The plantar orthosis has been well tolerated by patients as it has been specially created to avoid encumbrance inside the shoe and without compressing the micro-circulation, with potential related risks. We also recommended the use of a shoe suitable for this category of patients, a shoe that did not have internal conflicts with the foot (seam, stitches, flaps) and that favoured the propulsion phase during walking through the sole. In addition, screening and monitoring can be considered once again a fundamental tool in preventive procedures, as well to track and evaluate not only physically active and athletic populations, but also clinical patients (Francavilla et al., 2016; Francavilla et al., 2020; Cesanelli et al., 2021). We have wagered a lot on changing patients' lifestyle habits by administering the training schedule to be carried out at home and through an electronic follow-up in close contact. In cases like this, a relationship of trust is established that will certainly lead to better outcomes.

The use of the stabilometric platform was of fundamental help for the realization of this study as it allowed to analyse the stability of the patients in the two follow-up times, creating data according to a standardized method.

CONCLUSIONS

In conclusion, we observed from the present study how the use of integrated techniques with the aid of digital instrumentation such as the stabilometric platform can open a new point of interest towards future research in this sector. The patient, placed at the centre of the research project, will not only acquire new knowledge about his state of health but be a source of new evidence on the treatments to be recommended in the daily clinical activity of our colleagues.

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