Diabetes Epidemiology and Management 5 (2022) 100040

Contents lists available at ScienceDirect

Diabetes Epidemiology and Management

journal homepage: www.elsevier.com

Original article

Impact of custom-made orthopedic footwear and plantar orthoses on quality of life and functionality of patients with diabetic neuropathic foot: A randomized clinical trial

Marta Botelho[a,c,*], Sandra Pais[a,b,c,d,e], Carla Guerreiro[c,e], Eduardo Fernández[f], Miguel Gonzalez[f]

[a] International Centre on Ageing, University of Algarve, Faro, Portugal
[b] Faculty of Medicine and Biomedical Sciences, University of Algarve, Faro, Portugal
[c] Algarve Biomedical Center – Research Institute, University of Algarve, Faro, Portugal
[d] Comprehensive Health Research Center, Nova Medical School, Lisbon, Portugal
[e] Program for a Long-lived Society, University of Algarve, Faro, Portugal
[f] University of Huelva, Huelva, Spain

ARTICLE INFO

Article History:
Received 10 September 2021
Revised 23 November 2021
Accepted 3 December 2021
Available online 7 December 2021

Keywords:
Diabetes mellitus
Type 2
Diabetic neuropathy
Foot orthoses
Shoes
Quality of Life

ABSTRACT

Aims: Determine the effectiveness of custom-made orthopedic footwear (OF) and total contact plantar orthoses (PO) on the quality of life (QoL) and functionality of people with type 2 diabetes with diabetic peripheral neuropathic (DPN).
Methods: Randomized clinical study with 2 parallel intervention groups and pre- and post-test analysis. In the standard footwear group (SFg), PO and education on foot self-care were applied and in the orthopedic footwear group (OFg) the same intervention was applied, but with personalized OF. A total of 43 type 2 diabetic patients with DPN aged 61 – 76 years were randomized: 20 in to SFg and 23 to OFg.
Michigan Neuropathy Screening Instrument (MNSI) was used to screen for DPN. QoL was assessed with Short Form–36 and functional level was evaluated by Lower Extremity Functional Scale (LEFS), 6 physical tests and center of pressure (CoP) oscillation.
Results: No differences in QoL were found between groups. OFg showed a better functional reach and mediolateral displacement of CoP ($p \leq 0.05$).
Conclusions: The OF does not show evidence on functional and QoL improvement in low-risk type 2 diabetic patients with neuropathy but both groups improved significantly in functional tests. The PO showed clinical value in these patients, so a regular and specialized treatment with appropriate footwear and plantar orthoses can play an important role in reducing the complications of diabetic neuropathy.

1. Introduction

Diabetes Mellitus (DM) is a chronic disease and one of the fastest growing global health emergencies of the 21st century, that has reached alarming levels, today, nearly half a billion people are living with diabetes worldwide [1]. When looking at this reality within the Portuguese population, in 2018 the estimated prevalence of DM was 13.6% [2].

Chronic hyperglycemia has been associated with specific chronic complications, that results in damage or failure of various organs, particularly eyes, kidneys, nerves, heart, and blood vessels [1].

Diabetic peripheral neuropathy (DPN) is the most common form of diabetes-related neuropathy and affects the distal nerves particularly in the feet [1], however more than 50% of DPN may be asymptomatic [3]. Foot problems in diabetes are among the most serious

Abbreviations: 6MWT, Six Minutes Walk Test; AP_D, Anteroposterior Displacement; BMI, Body Mass Index; BP, Body Pain; CoP, Center of Pressure; DM, Diabetes Mellitus; DPN, Diabetic Peripheral Neuropathic; EP, Emotional Performance; FRT, Functional Reach Test; GH, General Health; HRQoL, Health Related Quality of Life; LEFS, Lower Extremity Functional Scale; LF, Left Foot; LOPS, Loss of Protective Sensation; LP, Length of Path; MH, Mental Health; ML_D, Mediolateral Displacement; MMSE, Mini Mental State Examination; MNSI, Michigan Neuropathy Screening Instrument; MSM, Mental Summary Measure; OF, Orthopedic Footwear; OFg, Orthopedic Footwear group; PF, Physical Function; PO, Plantar Orthoses; PP, Physical Performance; PSM, Physical Summary Measure; QoL, Quality of Life; RF, Right Foot; ROM, Range of Motion; SA, Sway Area; SF, Social Function; SFg, Standard Footwear group; TST, Tandem Stance Test; TUG, Time Up and Go Test; TWT, Tandem Walk Test; UST, Unipedal Stance Test; VCOP, Velocity of Center of Pressure; VT, Vitality

* **Corresponding author at**: International Centre on Ageing, University of Algarve, Faro, Portugal

E-mail addresses: mcbotelho@ualg.pt, mcbotelho@ualg.pt (M. Botelho), spais@ualg.pt (S. Pais), csguerreiro@ualg.pt (C. Guerreiro), eduardo.molina@denf.uhu.es (E. Fernández), miguel.pedregal@denf.uhu.es (M. Gonzalez).

https://doi.org/10.1016/j.deman.2021.100040

complications of the disease and a source of major suffering and costs for the patient, healthcare, and society in general [4].

People with DPN in general, have functional changes and worse physical performance, compared to the healthy population, due to nerve conduction dysfunction caused by the damage of nerve fibers [5]. These patients normally show greater instability and superior displacement of the center of pressure (CoP) [6,7], poor mobility and altered gait pattern, [8] which consequently may increase the fall risk [9].

The psychosocial burden of living with diabetes is often high, and can affect self-care behavior, with the risk of developing complications and decreased quality of life (QoL) [10]. The presence of DPN is strongly associated with a reduction in QoL in all domains [12]. Additionally, people with type 2 diabetes show worse perception of health-related QoL (HRQoL) compared to healthy people, mainly in physical function, body pain and social function [11].

Offloading of feet regions is a key area of managing the diabetic foot in terms of preventing and healing ulcers. The primary goal of offloading plantar orthoses (PO) is to redistribute the plantar pressure or reduce the compression, traction, or shear forces on the feet, thus relieving the overload zones of pain, hyperkeratosis, ulceration, others and minimizing their damaging effects [13].

Inappropriate footwear is one of the principal risks factors for ulceration. Calluses or ulcerations are often a consequence of continued trauma from inadequate footwear [14]. For greater efficacy in the treatment of diabetic foot it is necessary that, together with PO appropriate footwear is used [15].

Standard footwear (for example sports or walking shoes) currently account for 70% of prescribed shoes and can offer a mechanically viable solution, as well as being cosmetically acceptable to patients [16].

In the medical literature, the importance of a “good footwear” for a foot with loss of protective sensation (LOPS) is emphasized, however, until now, research has focused on only one part of the problem, mainly in the reduction of plantar pressure, but there are still no holistic approaches to conservative treatment with footwear and PO.

Thus, this study may help to clarify the impact that orthopedic footwear and plantar orthoses have on health-related quality of life, and functional capacity of patients with DPN and additionally clarify decision-making in medical prescription.

This Randomized Clinical Trail considers that orthopedic treatment using custom-made OF and a personalized PO, which reduces plantar pressure and aligns the foot and ankle, allows a better level of HRQoL and improves the functional level of people with DPN, compared to standard treatment.

Research design and methods

Study design and randomization

This Randomized Clinical Trial (RCT) was prepared in accordance with the SPIRIT statement and the guidelines of the CONSORT. The present RCT includes 2 parallel intervention groups with a pre- and post-test analysis. The non-probabilistic sampling procedure and a convenience sampling plan was chosen.

During recruitment, subjects were numbered according to the order of their assessment and the random allocation sequence was a selection of 23 random numbers without repetition.

Both intervention groups were evaluated at two different time: pre-test (T0 - Baseline) and post-test at 4 months after the intervention (T4). In the middle, at two months (T2) a questionnaire by phone was applied to understand the adherence and the self-perception of intervention.

Written informed consent was obtained from the participants before data collection. The study was approved by the Ethics Committee for Health of Regional Health Administration of Algarve and by National Data Protection Commission. This Trial was registered at http://www.clinicaltrials.gov (NCT04605900).

Setting and participants

The trial was conducted between March of 2017 and May of 2018. Inclusion criteria was adults with type 2 diabetes, DPN and no history of OF and PO use. A community sample of 90 subjects, were recruited from 2 entities: AEDMADA (Association for the study of diabetes mellitus and support for diabetics in the Algarve) and from The Grouping of Health Centers of Central Algarve (ACES-Central).

A total of 43 subjects were accepted to participate in this RCT, 47 were exclude for pre-established exclusion criteria: active ulceration; severe foot deformities; presence of cognitive impairment; gait with technical devices; diagnosis of neurological disease that can affect the gait pattern; diagnosis of another disease that can negatively influence the study, like depression, uncontrolled cardiovascular diseases and active cancer; surgical interventions on the spine and lower limbs, with less than 1 year of recovery.

The DPN screening was performed by the Portuguese version of the Michigan Neuropathy Screening Instrument (MNSI) [17] and cut-off points of MNSI questionnaire (Q) ≥ 4.0 and/or MNSI Examination (E) ≥ 2.5 were used [18].

To identify subjects with cognitive impairment which may affect their ability to answer questions independently, the Mini Mental State Examination (MMSE) was applied, and subjects were exclude according to Portuguese Cut-offs [19].

Subject’s physical features were collected including age, gender, body mass index (BMI), diabetes duration, glycated hemoglobin (HbA1c), ankle range of motion (ROM) (universal goniometer), maximum isometric muscle strength of plantar flexors and dorsiflexors (handheld dynamometer – Lafayette Instrument model 01163), Hernández-Corvo Index (pedigraphy with *Harris-Beath)* and foot deformities.

A 7-item questionnaire to assess the foot self-care practices (inspection and hygiene) was designed by the investigator based on *International Working Group on the Diabetic Foot* (IWGDF) *Guidance* 2015 [4] and a norm of Directorate-General of Health (DGS) N°005/2011.

Interventions

For all customized molded orthoses (control and experimental), foot shape was molded from neutral–suspension plaster casts with the subtalar joint placed in the neutral position and a dorsiflexive force was applied to the heads of the fourth and fifth metatarsals [20]. Manufacture of orthoses was designed to be a total contact plantar orthosis and the positive cast was modified based on the barefoot plantar pressure distribution contours in pedigraphy. For this study, the orthoses design focused on longitudinal arch support and offloading the submetatarsal head region.

A 3 mm top cover of ethylene vinyl acetate (EVA) foam (shore A 20 durometer) and flexible polyurethane filling (expandable) ELAX were applied to give similar characteristics to human adipose tissue, with the ISO 180 isocyanate catalyst. All materials were provided by OKM Química Ortopédica SL. The custom-made PO were strictly customized and all craft-made by the same experienced orthopedic technician.

Subjects of OFg were offered a custom-made OF manufactured by J. Andrade Ferreira Neves Lda., all with the same materials and same manufactured procedures. The OF were a soft thermoformable leather to adapt to deformities, with extra depth to fit customized PO and with stiff outsole.

All subjects in the SFg were given recommendation about the most appropriate footwear (walking or sports shoes) that could accommodate the PO. It was a free decision of each participant to change to this type of shoe, as recommended in international guidelines and norms of standard care/treatment [4].

The orthoses and shoes could be adjusted at any point during the trial, but they could not be modified to alter the plantar offloading properties.

Before the participants started the 4 months of intervention, written instructions for a progressive wearing–in schedule and information about foot care were provided to ensure that the participants continued with these good practices, and to ensure that the devices materials maintain their properties during the intervention.

Farther, each participant was given a 100 ml Pedi-Relax Diabetic Foot cream, provided by the company Pierre Fabre Portugal, to encourage and motivate the participants to follow self-care with their feet.

Outcomes

HRQoL was measured with the Medical Outcomes Survey Short Form-36 (SF-36). The SF-36 consists of 36 individual questions (items) aggregated into eight dimensions (physical function (PF), physical performance (PP), emotional performance (EP), body pain (BP), general health (GH), vitality (VT), social function (SF) and mental health (MH)) on a scale of 0–100, where a higher score equates with greater well-being [21]. The SF-36 is an accurate, valid, and reliable means of measuring QoL [21,22,23].

The functional assessment protocol was configured as a circuit with seven stations: 1) Lower Extremity Functional Scale (LEFS) [24]; 2) Functional Reach Test (FRT); 3) Unipedal Stance Test (UST); 4) Tandem Stance Test (TST); 5) Tandem Walk Test (TWT); 6) Time Up and Go (TUG) Test; 7) Six Minutes Walk Test (6MWT). The functional assessment took approximately 20 min per participant.

Postural Control was assessed through the oscillation of CoP. Sway Area (SA), Length of Path (LP), mediolateral and anteroposterior displacement (ML_D and AP_D) and COP Velocity (V_{COP}) were calculated. The freeMed® baropodometric platform and the freeStep® software version 1.4.01 from the company SensorMédica® was used. The acquisition frequency was 25 Hz. The participants remained static for 30 s, with the arms extended along the body and with a comfortable and self-selected support base. Subjects were assessed with eyes open fixing a point 2 m away and in three conditions: barefoot, Footwear + PO and PO.

Adherence to treatment and satisfaction was assessed using a closed response questionnaire designed for this purpose.

Data management and statistical analyses

Descriptive statistics were calculated to characterize the study sample in IBM SPSS Statistics version 24. Normality of data distribution was assessed by Shapiro-Wilk Test.

In the independent quantitative measures with normal distribution and homogeneity of variances (Levene's test, $p>0.05$) the Student *t*-test was applied. When the assumption of variances was not satisfied, the Welch procedure was used. Mann-Whitney U Test was applied for measures with non-normal distribution.

In the repeated quantitative measures with normal distribution, the Student *t*-test was applied. In cases of non-normal distribution, the non-parametric Wilcoxon test was used. The treatment effect was based on statistical significance of 0.05.

To compare independent qualitative measures, Pearson's Chi-Square test (χ^2) was applied. For repeated measures, the McNemar test was used.

Table 1
Baseline characteristics.

		OF Group	SF Group	*p*-value
Number of subjects		23	20	
Male subjects		16 (69.6)	11 (55.0)	0.324
Age (years)		68 ± 7	70 ± 7	0.394
Body Mass Index (kg/m^2)		29.9 ± 4.2	30.3 ± 4.6	0.685*
Diabetes duration (years)		12.8 ± 8.6	15.0 ± 9.9	0.486*
MNSI (score)				
Questionnaire		3.8 ± 2.8	3.6 ± 3.1	0.722*
Examination		4.0 ± 1.6	4.2 ± 1.3	0.392*
MMSE (score)		27.6 ± 2.1	28.3 ± 1.4	0.351*
HbA1c				
%		6.8 ± 1.2	7.3 ± 1.4	0.307
mmol/mol		51.9 ± 3.3	56.4 ± 3.6	
Ankle ROM (angle)				
Flexion	RF†	8 ± 8	8 ± 5	0.509*
	LF†	10 ± 2	6 ± 5	**0.031***
Extension	RF	43 ± 8	42 ± 7	0.677*
	LF	43 ± 7	40 ± 9	0.231
Peak Muscle Strength (kg)				
Dorsiflexors	RF	8.8 ± 3.3	9.1 ± 5.0	0.687*
	LF	9.2 ± 2.9	8.5 ± 3.5	0.466
Plantar flexors	RF	7.3 ± 2.7	8.9 ± 5.2	0.562*
	LF	7.0 ± 3.4	8.5 ± 4.5	0.203*
Hernández-Corvo Index	RF	56.4 ± 11.3	60.2 ± 11.2	0.184*
	LF	58.3 ± 8.5	61.9 ± 11.1	0.224
Arch Foot				
High	RF	10 (43.5)	12 (60.0)	0.710
	LF	9 (39.1)	13 (65.0)	
Normal	RF	6 (26.1)	3 (15.0)	
	LF	7 (30.4)	5 (25.0)	0.112
Flat	RF	7 (30.4)	5 (25.0)	
	LF	7 (30.4)	2 (10.0)	
Foot deformities				
Hallux Valgus	RF	11 (47.8)	13 (65.0)	0.258
	LF	8 (34.8)	13 (65.0)	**0.048**
Claw Toes	RF	9 (39.1)	8 (40.0)	0.954
	LF	9 (39.1)	8 (40.0)	0.954
Hammer Toes	RF	0 (0.0)	0 (0.0)	–
	LF	2 (8.7)	1 (5.0)	0.635

Values are mean ± SD or n (%).
* U Mann-Whitney test.
† RF – right foot; LF – left foot.

Results

Participant characteristics

Between January 2018 and May 2018, 90 adults were screened for inclusion. Of these, 43 (47.8%) fulfilled the inclusion criteria and agreed to participate in the trial, 23 were randomized to custom OF and PO and 20 to the SF and PO.

Physical characteristics of each group were mostly similar at baseline (Table 1).

The sample ($n = 43$) revealed a mild/moderate neuropathy with an average score of 3.7 ± 2.9 (Q) and 4.1 ± 1.6 (E).

Regarding foot inspection, although 79% ($n = 34$) were able to reach their own feet, only 67% ($n = 29$) claim to observe their feet regularly and of these, only 48% ($n = 21$) do this every day, additionally only 47% ($n = 20$) inspect between their interdigital spaces. The SFg showed more ability to visualize their feet than OFg (85% vs 52%; $p = 0.022$). On hygiene practices, 86% ($n = 37$) performed daily foot washing, but only 40% ($n = 17$) applied cream on their feet daily. About 54% ($n = 23$) say that do not look for help of any health professional when they have a problem with their feet.

No participant wore custom-made footwear. Regarding standard footwear, 63% ($n = 27$) used boots, 44% ($n = 19$) sports footwear and 21% ($n = 9$) moccasin shoes. Considering open shoes, 54% ($n = 23$) wore slippers and 42% ($n = 18$) sandals.

The use of sports shoes (65% vs 26%; $p = 0.010$) and slippers (75% vs 35%; $p = 0.008$) was more frequent in SF group.

Table 2
Quality of life and functionality outcomes.

Outcomes	Post-Intervention		*p*-value		
			Intra Group		Inter Group
	SF Group	OF Group	SF	OF	
SF-36 (score)					
PF	72.4 ± 20.9	69.0 ± 22.1	0.068	0.087	0.640
PP	82.4 ± 19.4	74.5 ± 21.7	0.662*	0.735*	0.283*
BP	58.5 ± 25.2	49.0 ± 23.1	0.300*	0.233*	0.257*
GH	49.9 ± 15.9	42.5 ± 13.3	0.913	0.235	0.130
VT	57.0 ± 23.5	53.1 ± 24.5	0.409	0.480*	0.460*
SF	85.3 ± 21.8	80.6 ± 23.1	0.937*	0.437*	0.619*
EP	85.8 ± 18.8	69.2 ± 28.4	0.219*	0.068*	0.091*
MH	69.4 ± 21.1	63.3 ± 21.6	0.182	0.119	0.388
PSM	44.2 ± 10.3	41.2 ± 8.9	0.872	0.419	0.351
MSM	53.4 ± 10.8	50.5 ± 11.4	0.407*	0.079	0.357*
Functional Assessment					
LEFS (score)	58.1 ± 15.7	54.7 ± 15.4	**0.049**	0.321	0.509
FRT (cm)	30.7 ± 4.3	33.3 ± 3.7	>**0.001**	0.263*	**0.042***
UST(s) RF	17.4 ± 10.8	22.1 ± 9.7	**0.011***	>**0.001***	0.283*
LF	18.9 ± 11.6	20.9 ± 9.2	**0.002***	**0.001***	0.517*
TST (s)	29.8 ± 1.0	28.5 ± 4.7	**0.024***	**0.005***	0.821*
TWT (steps)	8.5 ± 2.4	9.4 ± 1.5	**0.037***	**0.065***	0.209*
TUGT (s)	9.1 ± 1.6	9.0 ± 2.3	**0.001***	**0.009***	0.557*
6-MWT (m)	513.4 ± 78.2	470.1 ± 102.4	**0.005**	**0.065***	0.187*
Postural Control – Footwear + OP					
SA (mm^2)	216.8 ± 56.0	64.5 ± 87.8	0.586*	0.079*	0.060*
LP (mm)	130.8 ± 126.9	207.6 ± 32.0	<**0.001**	**0.001**	0.555
D_ML (mm)	10.0 ± 5.4	6.3 ± 3.3	0.076*	0.881*	**0.021**
D_AP (mm)	13.1 ± 8.1	9.6 ± 8.3	0.381*	0.218*	0.069*
V_{COP} (mm/s)	7.3 ± 1.9	7.0 ± 1.1	<**0.001**	**0.001***	–

Values are mean ± SD.
* U Mann-Whitney test or Wilcoxon Test (Paired Samples).
PF – Physical Function; PP – Physical Performance; EP – Emotional Performance; BP – Body Pain; GH – General Health; VT – Vitality; SF – Social Function; MH – Mental Health; PSM – physical Summary Measure; MSM - Mental Summary Measure; FRT – Functional Reach Test; UST – Unipedal Stance Test; TST – Tandem Stance Test; TWT – Tandem Walk Test; TUG – Time Up and Go Test; 6MWT – Six Minutes Walk Test; SA – Sway Area; LP – Length of Path; ML_D – Mediolateral Displacement; AP_D – Antero-posterior Displacement; VCOP – COP Velocity; RF- Right Foot; LF – Left Foot.

Outcomes

Eight–six (86%) participants were followed up at 4 months.

At baseline and after intervention in QoL, no statistically significant differences between groups were observed (Table 2).

For functional performance, FRT ($p = 0.042$) and ML displacement ($p = 0.021$) with footwear+OP showed significant differences between groups. In the remaining functional tests, although no significant differences were observed, both groups improved the functional performance (Table 2).

There were no significant differences in adherence to the intervention or in the level of satisfaction between groups. 81% ($n = 17$) of OFg used the PO and OF ≥ 4 times a week but 57.1% ($n = 12$) used them ≤ 8 h per day. In SFg, 94,1% ($n = 16$) used the OP with their appropriate footwear ≥ 4 times a week but 29.4% ($n = 5$) used them ≤ 8 h per day. All participants ($n = 37$, 100%) had a self-perception of improvements in their feet/legs and most of them were satisfied ($n = 36$, 95.2%).

Conclusions

The subjects were over 60 years of age, which is not surprising once the prevalence of DM increases with age.

Reduced values of ROM and muscle strength were observed. Joint stiffness and reduced mobility have been described as key factors underlying in foot biomechanics changes in patients with DM and DPN, due to the collagen glycolisation of joint capsules and ligaments [25, 26], and muscle weakness, which in more advanced stages may cause muscle atrophy and deformities [27, 28]. Approximately 50% of subjects had high arch feet, which may be related to the loss of muscle strength observed [29].

Our data showed that the subjects in the OFg were less capable to inspect their feet. A previous study by Rocha et al. [30] also found that 81.8% ($n = 45$) of subjects they studied with DM, reported to have acknowledge that their feet should be examined daily, however only 33% had the habit of doing so.

Most of the subjects used closed shoes, but a very significant percentage also uses open shoes. Only 13% of DM patients say they wear special shoes because of their condition [31].

Analyzing the results of QoL, we concluded that, for low-risk patients, custom-made OF does not provide additional benefits to SF. Although the physical performance component improved in both groups, no statistical significance was found between groups. Nonetheless the OFg showed an unfavorable evolution, with emphasis on emotional performance and mental summary measure. This change may be due to the imposition of changing habits, namely in the type of footwear, which differed considerably from the one they used habitually, and this can be seen as a stress triggering factor. From this perspective it is crucial to know the fears and expectations of patients when applying a particular treatment. However, there is not much evidence about this topic, and some of them seem to be contradictory [32, 33].

At 4 months there were not many evidence of the effect of OF, but the significant improvement observed in balance of OFg, may be due to the sole type of the custom-made orthopedic footwear, as this is more rigid and larger, allowing the entire foot to be in contact with the floor, increasing stability and balance. Most of the SFg subjects used sports shoes that contain rockers in the sole which are known to induce poor balance [34].

Both groups showed functional reach values higher than the cut-off point for the fall risk in DNP (≤ 25.4 cm) [34] after the intervention. There was a significant improvement in static and dynamic balance (UST, TST and TWT) in both groups. It is known that the PO reduces the degree of hyperkeratosis [36], which consequently can reduce pain and improve balance [37]. This may possibly be the answer to the improvement founded, however, the evolution of the degree of hyperkeratosis was not assessed during the study. In mobility (TUG test) we also observed improvements in the groups, which after the intervention reached values below the cut-off point for the fall risk in subjects with DPN (≥ 10.7 s) [35].

Because both groups improved significantly in functional tests (balance, mobility and functional reach) and the use of PO was common in both groups, PO may justify the improvements founded in both groups, once no significance was found between groups to justify the additional use of OF.

On the other hand, significant differences in between groups were only observed in the FRT. The SF group used standard sports or walking shoes, which are more accessible and cheaper, stressing that it may not be justified to prescribe additional orthopedic shoes in addition to the insoles provided to these patients if they adopt the use of standard sports or walking shoes.

For type 2 diabetic patients with low-risk neuropathic feet, international guidelines recommend well-equipped walking/sports shoes, which cushion the impact during gait and custom-made PO for the ulceration prevention [3,4, 38], although these guidelines are strongly recommended but they have not scientific evidence [39]. Thus, our results hep to sustain these guidelines.

In the absence of evidence about OF prescription to low-risk neuropathic feet, many decisions are based on the experience of daily clinical practice. This study helps to understand the impact that OF has on the DM related health measures and to clarify decision-making in medical prescription. Therefore, the cost-effectiveness of prescribing orthopedic footwear in low-risk patients should be studied, since functional improvements do not seem to justify the monetary investment. Regardless of these conclusions, it is always necessary to evaluate and adapt these considerations to patient.

The fact that the appropriate footwear showed in this study a good performance, reinforces the need for patient's education and guidance on choosing an appropriated shoe. Additionally, there are a variety of structural changes that can be made in standard footwear, namely the use of internal supports (PO), rocker soles or corrective wedges, which can solve in advance a series of problems that may affect the QoL in the future.

Thus, in our opinion, it is imperative to rethink the primary health care organization for diabetic foot. The need to involve orthopedic technicians specialized in footwear and PO adaptations in level I of health care services, is urgent to delay/avoid the manifestation of serious future complications in patients with DM.

This RCT showed some methodological limitations: sampling was non-probabilistic and sample size was small and not representative of patients with diabetes in Portugal. It would have been important to have assessed the presence and evolution of plantar hyperkeratosis, since this may be related to the positive modification of functionality observed.

In future studies it is relevant to understand the influence that PO and footwear materials densities may have on balance and postural control in subjects with DM and DPN, once there is a studies gap on the influence of sports shoes in patients with DM.

Authors' contributions

MB participated in the data collection, analyzing and interpreting the data, and writing the manuscript. CG participated in the data collection and assisted in interpreting the data. SP and MG helped to plan the study design and reviewed/edited the manuscript. EF and MG contributed to statistical analysis and wrote the results. All the authors revised preliminary versions of the manuscript and read and approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

The authors thank Marisa Almeida, Susana Costa, Rui Lourenço and Sara Zorrinha from ACES Central – Primary Health Care Centers for the precious collaboration in the field work.

We would like to deeply thank the collaborating of the following companies: Instituto São João de Deus, OKM – Química Ortopédica, Lola – J. Andrade Ferreira Neves, Sensor Médica and Pierre Fabre Portugal. This work was supported by the CENIE (International centre on Ageing) [grant number 0348_CIE_6_E].

References

[1] International Diabetes Federation. IDF Diabetes Atlas. 8th editor IDF (ed.) 2017. Available from: doi: http://dx.doi.org/10.1016/S0140-6736(16)31679-8.
[2] Sociedade Portuguesa de Diabetologia. Diabetes: factos e Números 2016, 2017 e 2018. Rev Portug Diabetes 2020;15(1):1–107.
[3] American Diabetes Association. Microvascular complications and foot care: standards of medical care in Diabetes-2020. Diabetes Care 2020;43(Suppl. 1): S135–51 Available from:. doi: 10.2337/dc20-S011.
[4] International Working Group on the Diabetic Foot. Prevention and management of foot problems in diabetes: a Summary Guidance for daily practice 2015. Available from: http://iwgdf.org/guidelines/summary-guidance-for-the-daily-practice-2015/ [*Accessed*: 28*th July* 2016]
[5] Strotmeyer ES, Rekeneire S, Schwartz AV, Faulkner KA, Resnick HE, Goodpaster BH, et al. The relationship of reduced peripheral nerve function and diabetes with physical performance in older white and black. Diabetes Care 2008;31(9):1767–72 Available from:. doi: 10.2337/dc08-0433.A.I.V.
[6] Vaz MM, Costa GC, Reis JG, Junior WM, De Paula FJA, Abreu DC. Postural control and functional strength in patients with type 2 diabetes mellitus with and without peripheral neuropathy. Arch Phys Med Rehabil 2013;94:2465–70 Available from:. doi: 10.1016/j.apmr.2013.06.007.
[7] Lim K-B, Kim DJ, Noh J, Yoo J, Moon JW. Comparison of balance ability between patients with type 2 diabetes and with and without peripheral neuropathy. PM R 2014;6(3):209–14 Available from:. doi: 10.1016/j.pmrj.2013.11.007.
[8] Sawacha Z, Gabriella G, Cristoferi G, Guiotto A, Avogaro A, Cobelli C. Diabetic gait and posture abnormalities: a biomechanical investigation through three dimensional gait analysis. Clin Biomech 2009;24:722–8 Available from:. doi: 10.1016/j.clinbiomech.2009.07.007.
[9] Schwartz AV, Vittinghoff E, Sellmeyer DE, Feingold KR, Rekeneire N, Strotmeyer ES, et al. Diabetes-related complications, glycemic control, and falls in older adults. Diabetes Care 2008;31(3):391–6 Available from:. doi: 10.2337/dc07-1152.
[10] Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev 1999;15:205–18 Available from:. doi: 10.1002/(SICI)1520-7560(199905/06)15:3<205::AID–DMRR29>3.0.CO;2-O.
[11] Hervás A, Zabaleta A, Miguel G, Beldarrain O, Díez J. Calidad de vida relacionada con la salud en pacientes con diabetes mellitus tipo 2. An Sist Sanit Navar 2007;30(1):45–52.
[12] Venkataraman K, Wee HL, Leow MKS, Tai ES, Lee J, Lim SC, et al. Associations between complications and health-related quality of life in individuals with diabetes. Clin Endocrinol 2013;78:865–73 Available from:. doi: 10.1111/j.1365-2265.2012.04480.x.
[13] Foster AVM. Offloading the diabetic foot. Podiatric assessment and management of the diabetic foot. London: Elsevier; 2006. p. 93–129.
[14] Direcção Geral de Saúde. Organização de cuidados, prevenção e tratamento do Pé Diabético. Orientação da Direcção Geral de Saúde (003/2011) 2011 Available from: http://www.dgs.pt/directrizes-da-dgs/orientacoes-e-circulares-informativas/orientacao-n-0032011-de-21012011.aspx.
[15] Healy A, Naemi R, Chockalingam N. The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors associated with diabetic foot ulceration: a systematic review. J Diabetes Complicat 2013;27:391–400 Available from:. doi: 10.1016/j.jdiacomp.2013.03.001.
[16] Munro W. Orthotic prescription process for the diabetic foot. Diabetic Foot 2005;8(2):72–82.
[17] Botelho MC, Pais SC, Fernández EM, González MP. Translation and cross-cultural adaptation of the measuring instrument Michigan neuropathy screening instrument for the portuguese population. Arch Diabetes 2019;1(2):020–5.
[18] Herman WH, Pop-Busui R, Braffett BH, Martin CL, Cleary PA, Albers JW, et al. Use of the Michigan neuropathy screening instrument as a measure of distal symmetrical peripheral neuropathy in type1 diabetes: results from the diabetes control and complications trial/epidemiology of diabetes interventions and complications. Diabet Med 2012;29(7):937–44 Available from:. doi: 10.1111/j.1464-5491.2012.03644.x.
[19] Santana I, Duro D, Lemos R, Costa V, Pereira M, Simões MR, et al. Mini-mental state examination: avaliação dos novos dados normativos no rastreio e diagnóstico do défice cognitivo. Acta Med Port 2016;29(4):240–8 Available from:. doi: 10.20344/amp.6889.
[20] Michaud T.C.*Foot Orthoses and Other Forms of Conservative Foot Care*. Massachusetts; 1997.
[21] Ferreira PL, Ferreira LN, Pereira LN. Medidas sumário física e mental de estado de saúde para a população portuguesa. Rev Port Saúde Publica 2012;30(2):163–71 Available from:. doi: 10.1016/j.rpsp.2012.12.007.
[22] Norris SL, McNally TK, Zhang X, Burda B, Chan B, Chowdhury FM, et al. Published norms underestimate the health-related quality of life among persons with type 2 diabetes. J Clin Epidemiol 2011;64(4):358–65 Available from:. doi: 10.1016/j.jclinepi.2010.04.016.
[23] Ahroni JH, Boyko EJ. Responsiveness of the SF-36 among veterans with diabetes mellitus. J Diabetes Complicat 2000;14(1):31–9 Available from. doi: 10.1016/S1056-8727(00)00066-0.
[24] Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. Phys Ther 1999;79(4):371–83.
[25] Deschamps K, Matricali GA, Roosen P, Nobels F, Tits J, Desloovere K, et al. Comparison of foot segmental mobility and coupling during gait between patients with diabetes mellitus with and without neuropathy and adults without diabetes. Clin Biomech 2013;28(7):813–9 Available from:. doi: 10.1016/j.clinbiomech.2013.06.008.
[26] Martinelli AR, Mantovani AM, Nozabieli AJL, Ferreira DMA, Barela JA, Camargo MR, et al. Muscle strength and ankle mobility for the gait parameters in diabetic neuropathies. Foot 2013;23(1):17–21 Available from:. doi: 10.1016/j.foot.2012.11.001.
[27] Andreassen CS, Jakobsen J, Andersen H. Muscle weakness: a progressive late complication in diabetic distal symmetric polyneuropathy. Diabetes 2006;55(3):806–12.
[28] Andersen H. Motor dysfunction in diabetes. Diabetes Metab Res Rev 2012;28 (Suppl. 1):89–92 Available from:. doi: 10.1002/dmrr.2257.
[29] Burns J, Redmond A, Ouvrier R, Crosbie J. Quantification of muscle strength and imbalance in neurogenic pes cavus, compared to health controls, using hand-held dynamometry. Foot Ankle Int 2005;26(7):540–4 Available from:. doi: 10.1177/107110070502600708.
[30] Rocha RM, Zanetti ML, Santos MA. Comportamento e conhecimento: fundamentos para prevenção do pé diabético. Acta Paul Enferm 2009;22(1):17–23.
[31] Gayle KAT, Reid MKT, Francis NOY, McFarlane SR, Weight-Pascoe RA, Wilks MSB, et al. Foot care and footwear practices among patients attending a specialist diabetes clinic in Jamaica. Clin Pract 2012;2(e85):216–20 Available from:. doi: 10.4081/cp.2012.e85.

[32] Davies S, Gibby O, Phillips C, Price P, Tyrrell W. The health status of diabetic patients receiving orthotic therapy. Qual Life Res 2000;9:233–40.
[33] Burns J, Wegener C, Begg L, Vicaretti M, Fletcher J. Randomized trial of custom orthoses and footwear on foot pain and plantar pressure in diabetic peripheral arterial disease. Diabetic Med 2009;26(9):893–9 Available from:. doi: 10.1111/j.1464-5491.2009.02799.x.
[34] Landry SC, Nigg BM, Tecante KE. Standing in an unstable shoe increases postural sway and muscle activity of selected smaller extrinsic foot muscles. Gait Posture 2010;32(2):215–9.
[35] Jernigan SD, Pohl PS, Mahnken JD, Kluding PM. Diagnostic accuracy of fall risk assessment tools in people with diabetic peripheral neuropathy. Phys Ther 2012;92(11):1461–70.
[36] Colagiuri S, Marsden LL, Naidu V, Taylor L. The use of orthotic devices to correct plantar callus in people with diabetes. Diabetes Res Clin Pract 1995;28(1):29–34.
[37] Koepsell TD, Wolf ME, Buchner DM, Kukull WA, LaCroix AZ, Tencer AF, et al. Footwear style and risk of falls in older adults. J Am Geriatr Soc 2004;52:1495–501.
[38] Bakker K, Apelqvist J, Schaper NC. Practical guidelines on the management and prevention of the diabetic foot 2011. Diabetes Metab Res Rev 2012;28(Suppl.1):225–31 Available from:. doi: 10.1002/dmrr.2253.
[39] Bus SA, Armstrong DG, Van Deursen R, Lewis JEA, Caravaggi CF, Cavanagh PR. IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. Diabetes Metab Res Rev 2016;32(Suppl.1):25–36 Available from:. doi: 10.1002/dmrr.2697.