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PLANTAR PRESSURE RESULTS OF A COMBINED STRENGTHENING, STRETCHING AND FUNCTIONAL TRAINING PROGRAM FOR DIABETIC NEUROPATHIC PATIENTS: A RANDOMIZED CONTROLED TRIAL

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SUMMARY

We applied an intervention for diabetic patients with peripheral neuropathy (PN), to improve their foot rollover process during gait. Exercises for foot and ankle strengthening, increase in joint motion and gait training were applied to 26 DP patients, randomly assigned, twice a week, for 12 weeks, while 29 DP control patients continued to receive the recommended usual care for the same time period. The intervention protocol was completely described previously [1]. Plantar pressure and time series analysis selected variables described the foot rollover in 6 foot areas. Compaired to controls, the intervention results showed a delay in time-to-peak preassure on the heel suggesting a smoother heel contact; an increase in the peak pressure and pressure-time integral on midfoot suggesting an improvement in its function during the rollover; an anticipation of the lateral forefoot contact before the medial forefoot; and an increase in peak pressure and pressure-time integral on hallux and an increase in pressure-time integral on toes, suggesting a better function of these commonly compromised foot areas. It is important to highlight preventive actions towards DP patients in a long term period. **ClinicalTrials.gov NCT01207284**

INTRODUCTION

Foot complications caused by peripheral neuropathy (PN is a combination of ROM reduction restrictions, muscle atrophy, loss of sensation and changes in foot rollover process, that contribute to increase load and tissue damage. Preventive interventions are the most important approach to avoid plantar ulceration and amputations, the most devastating endpoint of the disease. Therapeutic interventions improve gait quality; however, there is no evidence of an effective physical therapy treatment for recovering musculoskeletal function and foot rollover during gait that could redistribute plantar pressure and potentially reduce the risk of ulcer formation. The aim of this study was to investigate the effect of exercise therapy intervention on foot rollover during gait. Our hypothesis were that a specific intervention to restore the normal function of foot and ankle would have a positive outcome in plantar pressure distribution in DP patients.

METHODS

A randomized controlled trial, with blind assessment and allocation, was designed to study the effect of a physiotherapy intervention on foot rollover. Fifty five neuropathic patients were randomized into control group (CG, n=29) and intervention group (IG, n=26). The intervention was carried out for 12 weeks, twice a week, for 40–60 minutes each session, and the complete description of the protocol is published elsewhere [1]. Plantar pressures distribution were recorded at baseline and after 12 weeks for both groups, using Pedar X (Novel, Germany), and the foot was divided in 6 areas (heel, midfoot, medial forefoot, lateral forefoot, hallux and toes) for analysis. The main outcome was peak plantar pressure (PP) and the secondary outcomes were pressure-time integral (PTI) and time to peak pressure (TPP). ANOVA two-way was used to compare group, time and interaction effects, considering α=5%. Cohen's *d* coefficients were calculated between CG and IG at 12 weeks to analyze intervention effects.

RESULTS AND DISCUSSION

The intervention provided changes in plantar pressure distribution (Table 1).During the heel strike, there was a delay of TPP at the heel (interaction effect), that represents a lower rate of loading and a better impact attenuation. There was also a medium effect of the increase in PTI after the intervention in the same area.Although our protocol mainly addressed strengthening of ankle and foot muscles, the gait training could have been efficient to achieve the more preserved proximal muscles, not compromised by DP, that are responsible for controlling the heel strike [2].A proper positioning of the heel is important in the initial contact sice it will influence the following position of all foot joints and segments during midstance and propulsion phases.

The higher PP and PTI at midfoot are a positive finding. The midstance of the gait of DP patients is known to be poor controlled, mainly due to impaired eccentric function of tibialis anterior, that is responsible for decelerating the forefoot until the midfoot touches the floor. The better control of this phase increase the participation of midfoot during rollover process.

When we observe the control group and the intervention group at baseline, their medial and lateral forefoot TPP occur at the same time, when ideally the lateral forefoot should receive plantar loads first [3]. The early TPP at lateral forefoot found after intervention also represents a more physiological foot rollover.

PP over the forefoot is of interest because there is a higher incidence of plantar ulcerations under this area and

because higher PP have been related to risk for plantar ulcerations [4]. In our study, the PP and PTI of forefoot areas did not reduced. For PP parameter, our groups were different at baseline condition and after 12 weeks. Both presented an increase in these two variables, reflecting a group and time effect, but no interaction effect.

PP and PTI over the hallux had increased after the intervention, suggesting more pronounced hallux contact. The proper load absorption throughout the foot segments, especially the medial forefoot, depends on the hallux to be functional to apply forces to the ground and propel the body forward. If the hallux is no longer active, the forefoot will have to assume this function and therefore will be overloaded [3].

PTI over the toes area presented an increase and a medium effect of PTI that is clinically relevant. A well described deformity of neuropathic patients are the claw toes, with marked weakness of intrinsic foot muscles [5]. The proper muscle balance provide stability and correct alignment of the toes and the metatarsal heads. That might have contributed to the plantar pressures results.

CONCLUSIONS

The exercises provided positive changes in the foot rollover. This protocol can be applied to every DP patient, regardless the stage of the disease, without tissue injuries. It is important to highlight the preventive action towards DP patients, because the complications in muscles and joints occur in a long term period, and it is of great importance to preserve their integrity.

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Table 1: Means and standard deviations for pressure variables before and after the intervention period.

Peak pressure (kPa) – Main Outcome

Foot areas	Control Group		Intervention Group		Intervention effect	
	Baseline (a)	12 weeks (b)	Baseline (c)	12 weeks (d)	Effect size[b-d] (Cohen`s d)	p (Interaction)
Heel	293.66[1] (68.49)	305.43 (64.31)	324.52[1] (87.99)	326.62[1] (74.49)	0.31 (small)	0.42
Midfoot	125.13[2] (63.68)	113.16[2] (61.37)	115.05 (43.40)	124.55 (47.17)	0.21 (small)	<0.01
Medial forefoot	313.43[3] (101.48)	328.71[4] (77.20)	358.84[3] (96.19)	373.68[3,4] (95.26)	0.52 (medium)	0.97
Lateral forefoot	297.96 (83.96)	307.18 (72.58)	321.41(78.80)	323.62 (68.16)	0.24 (small)	0.57
Hallux	214.83 (69.22)	229.71 (85.18)	209.79[5] (95.58)	237.36[5] (87.89)	0.09 (small)	0.43
Toes	180.61 (99.60)	173.93 (93.26)	187.77 (94.14)	203.76 (108.89)	0.30 (small)	0.25

Pressure time integral (kPa.s) – Secondary outcome

Foot areas	Control Group		Intervention Group		Intervention effect	
	Baseline (a)	12 weeks (b)	Baseline (c)	12 weeks (d)	Effect size[b-d] (Cohen`s d)	p (Interaction)
Heel	79.14 (22.35)	79.07 (17.31)	81.61 (25.90)	87.39 (23.02)	0.41 (medium)	0.12
Midfoot	42.94 (20.94)	38.83 (20.67)	36.99[6] (14.62)	42.39[6] (23.32)	0.16 (small)	<0.01
Medial forefoot	90.21 (28.35)	93.80 (20.56)	101.04 (29.30)	110.15[7] (29.51)	0.64 (medium)	0.182
Lateral forefoot	90.95 (24.65)	92.65 (20.50)	93.18 (21.74)	99.45[8] (25.33)	0.30 (small)	0.26
Hallux	48.69 (22.61)	50.61(19.24)	47.00 (20.96)	55.01[9] (20.30)	0.22 (small)	0.16
Toes	48.08 (24.14)	44.58 (22.69)	49.55 (23.96)	55.76 (29.08)	0.43 (medium)	0.07

Time to peak pressure (% of stance phase) - Secondary outcome

Foot areas	Control Group		Intervention Group		Intervention effect	
	Baseline (a)	12 weeks (b)	Baseline (c)	12 weeks (d)	Effect size[b-d] (Cohen`s d)	p (Interaction)
Heel	17.9 (6.0)	18.1(5.5)	17.1[6] (5.7)	19.9[6] (4.0)	0.38 (small)	0.01
Midfoot	54.2 (14.3)	53.5 (13.6)	51.3 (16.6)	51.1 (15.5)	0.17 (small)	0.89
Medial forefoot	81.9 (4.4)	82.1 (2.3)	81.8 (4.3)	81.5 (3.9)	0.19 (small)	0.48
Lateral forefoot	80.3 (4.6)	80.7 (3.1)	81.8[6] (3.5)	80.2[6] (3.6)	0.16 (small)	<0.01
Hallux	85.8 (5.2)	85.6 (3.6)	84.5 (8.9)	83.4 (9.0)	0.33 (small)	0.30
Toes	83.5 (6.0)	83.1(4.0)	83.1 (8.7)	81.8 (8.7)	0.19 (small)	0.46

[1] represents condition a is different from b and c (time effect, p=0.03); [2] represents condition a is different from b (interaction effect); [3]represents condition a is different from b and c (time effect, p=0.04); [4] represents condition b is different from d (group effect, p=<0,01); [5] represents condition c is different from d (time effect, p=0.01); [6] represents condition c is different from d (interaction effect); [7] represents the different condition from the others (time and group effect, p<0.01); [8] represents the different condition from the others (time effect, p=0.04).