

Diabetic Peripheral Neuropathy and Gait: Does Footwear Modify This Association?

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Abstract

Background:

Gait-related fall risk is the leading cause of mortality among patients with diabetes, especially those older than 65 years. Deterioration in balance and loss of protective sensation in lower extremities contribute significantly to fall risk in patients with diabetic peripheral neuropathy (DPN). This study aimed to explore the impact of neuropathy and foot ulcer on gait.

Methods:

We recruited 39 participants (age, 56.9 ± 8.2 years; body mass index, $29.6.3 \pm 4.7$ kg/m²), including 15 DPN patients without foot ulcers, 16 DPN patients with foot ulcers, and 8 healthy aged-matched controls. Patients with active foot ulcers wore an offloading device during gait examination, including removable cast walker.

Results:

Results suggest that neuropathy alters gait mainly by increasing gait initiation, gait variability (coefficient of variation of gait velocity), and double support (DS) time, while reducing knee range of motion and center of mass sway ($p < .05$). Interestingly, the presence of foot ulcer does not impact gait velocity ($p > .1$) but enhances some of the gait parameters such as gait variability and DS time.

Conclusions:

This study demonstrates that neuropathy deteriorates gait, but the presence of foot ulcers does not alter gait parameters further than neuropathy. In addition, patients with foot ulcers demonstrated a better gait compared with DPN patients without ulcers. We speculate that offloading footwear may be enhancing the somatosensory feedback from sensate skin, thereby positively affecting gait parameters. A study with a larger sample is required to explore the effect of prescribed footwear in the DPN population in order to validate the findings of this research study.

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Abbreviations: (BMI) body mass index, (COM) center of mass, (CV) coefficient of variation, (DPN) diabetic peripheral neuropathy, (DS) double support, (SD) standard deviation

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Introduction

Statistics from Centers for Disease Control and Prevention reported 2.3 million nonfatal fall injuries and over 650,000 patients being hospitalized from fall-related injury.¹ Fall risk is a leading cause of mortality among diabetes patients, especially those aged over 65 years. Falls result in serious bodily injuries, including fractures in the elderly population.² A number of studies have shown that gait changes in the elderly are related to high fall risk, including gait unsteadiness and gait variability, especially if they have history of falls,^{3–5} causing them to alter gait strategies in order to reduce fall risk.^{3,6} However, additional gait parameters, including variability in ground-foot clearance, have been linked to increased fall risk.⁷

There has been an increasing body of evidence highlighting the high rate of falls in diabetes patients.^{2,8–10} According to a survey, diabetes is one of the strongest predictors of high fall risk among the elderly.¹¹ Among several factors that contribute to high fall risk in patients with diabetes, deterioration in balance and loss of protective sensation in lower extremities are the most common.^{12,13} Loss of protective sensation [diabetic peripheral neuropathy (DPN)] is a common complication of diabetes, affecting more than 50% of elderly diabetes patients aged above 60 years.^{14,15} Other factors such as reduced speed, increased double support (DS) time, higher reaction time, changes in joint stiffness, reduced ankle joint moment, strength, higher vibration perception thresholds, lower gait velocity, and reduced muscle strength have also been linked to gait variations.^{9,14,16,17} Patients with DPN exhibit such gait changes as listed here and also have reduced ankle strength and are therefore 15 times more likely to report falls.^{18–20} These changes in gait may also exist and differ significantly in patients with or without neuropathic pain.²¹ Based on retrospective reports, Lalli and coauthors²¹ also found a nonsignificant increasing trend of number of falls and fall-related injuries.

Additionally, DPN is a major risk factor for developing diabetic foot ulcers. Early studies that focused on exploring gait variation between different groups with diabetes found significant difference in some gait and kinematic parameters, especially gait velocity between DPN with history of ulcer and diabetes controls; however, no significant gait changes were found between DPN with and DPN without ulcer history.²² It has been reported that, among a population of diabetes patients with a history of foot ulcer, fall risk is significantly associated with comorbidity, insensitive feet, and body mass index (BMI).²

After careful review of the literature, we determined the lack of studies on specific differences in gait parameter between DPN with and DPN without active foot ulcers. Additionally, some of the drawbacks of previous studies assessing gait on elderly and diabetes populations include measurements being performed either on a treadmill or inside a gait laboratory. Both these settings are not the actual environment where this population performs their activities of daily living and may also cause individuals to modify their gait pattern to adjust to the new environment. The current study was aimed to compare objective gait parameters, including gait velocity, gait initiation, and gait variability, among DPN patients with and without ulcer using wearable sensors that can be mounted unobtrusively on different body segments, allowing measurements to be done outside the laboratory, for instance, in a clinical environment or at home. Since gait parameters can change as a function of distance, speed, and environment, wearable sensors are therefore better suited for the proposed real-world measurements.^{23–25} Previous studies have demonstrated changes in gait termination in diabetes patients with peripheral neuropathy;²⁶ however, gait initiation is another aspect that needs attention and was addressed in this research. Gait initiation and termination are more complex procedures than steady-state walking and therefore may increase the risk of falls.²⁷

Methods

Subject Recruitment and Protocol

We recruited 39 study participants, 15 DPN patients without foot ulcers (age, 54.2 ± 11.3 years; BMI, 31.2 ± 5.9 kg/m²), 16 DPN patients with active foot ulcers (age, 58.3 ± 4.4 years; BMI, 29.5 ± 3.7 kg/m²), and 8 healthy controls (age, 59.6 ± 6 years; BMI, 27 ± 3.2 kg/m²). Ethical approval was received by the institutional review board, and all participants signed an informed consent form prior to participating in the study. Peripheral neuropathy in

diabetes patients was confirmed from patient records and additionally by using a 10 g monofilament test at multiple plantar foot locations per the recommended American Diabetes Association guidelines. Diabetes patients with major foot amputation(s) were excluded from the study. Participants with inability to walk 100 m without assistance were also excluded.

All study participants walked along a predefined path of approximately 200 ft. All diabetes subjects wore their prescribed footwear, including surgical sandals, removable cast walkers, and prescribed shoes. Out of 15 DPN patients without ulcer, 5 had a cast from diagnosed Charcot, 2 wore prescribed shoes, 6 wore regular shoes, and 2 wore offloading sandals. All 16 DPN patients with an active foot ulcer wore prescribed shoes, including cast, offloading sandals, and offloading removable cast. Healthy controls wore their habitual footwear.

A set of validated wearable sensors was used to collect gait data (LEGSys™, Biosensics LLC, MA). Gait was assessed by processing wearable sensor data, and various spatiotemporal parameters were extracted.²⁸ The method for calculating spatiotemporal parameters of gait and its validity has been previously described in detail.^{24,29–31} Based on statistical intercycle fluctuation of gait velocity, the beginning of gait steady state was objectively identified as described in our previous publications.^{27,32} In summary, the standard deviation (SD) of velocity of six successive strides (three right and three left strides) was calculated from the first stride (for example, SD of strides 1, 2, 3, 4, 5, and 6 and 2, 3, 4, 5, 6, 7, . . .). The marker of the beginning of steady-state walking was the first stride of the group of six strides with an SD below the median SD of the all analyzed strides $\pm 6\%$, related to the sensitivity of the sensors.²⁹ Additionally, gait steadiness and gait initiation was also quantified.^{24,32} In summary, for the purpose of this study, we focused on six gait parameters hypothesized to be the most important independent gait parameters that may be affected by neuropathy: (1) stride velocity, (2) stride length, (3) gait cycle time, (4) double stance presented as a percentage of gait cycle time, (5) motion of center of mass (COM) during walking estimated by the area of trunk sway during walking in medial–lateral and anterior–posterior, and (6) knee range of motion. All parameters listed here were averaged during both gait initiation as well as at least 10 strides during gait steady state. In addition, coefficient of variation (CV) of stride velocity during gait steady state was estimated as an indicator of gait variability. The CV of stride velocity was defined as the SD of measured stride velocities during steady state divided by the average of stride velocities multiplied by 100. Finally, to further quantify gait initiation phase, the number of steps and distance required to achieve gait steady state walking were estimated as described in earlier publications.^{24,27}

Results were analyzed in SPSS using multivariate analysis of variance analysis for comparing the three groups, and the statistical significance was set to $p = .05$. Between-group comparison was performed for gait parameters during gait initiation and gait steady-state phases.

Results

Tables 1 and **2** list the statistical comparison between groups based on multivariate analysis of variance and pairwise comparison for gait parameters, respectively, during gait steady state and during gait initiation phases. There was no significant difference for age between the groups ($p = .23$).

Gait Initiation Phase

Comparison of gait parameters during gait initiation phase revealed significant group differences for number of steps required to reach steady-state gait ($p = .009$), knee range of motion ($p = .003$), and CV for stride velocity ($p = .03$; **Table 1**).

We observed that the presence of neuropathy increases the number of steps required to reach steady state gait (i.e. gait initiation) by nearly 90% on average compared with healthy individuals ($p = .009$). Pairwise comparison revealed significant difference between both DPN without ($p = .005$) and DPN with foot ulcer ($p = .006$) compared with healthy individuals; however, no difference was found between the two DPN groups (**Figure 1**).

Table 1.
Between-Group Comparison during Gait Initiation Phase^a

Parameter	Group	Mean	SD	p value	Groups	Pairwise	95% confidence interval for difference	
Stride velocity, m/s	DPN no ulcer	0.83	0.30	0.13	1 and 2	0.76	-0.20	0.15
	DPN with ulcer	0.84	0.18		1 and 3	0.05	-0.43	0.00
	Healthy	1.02	0.19		2 and 3	0.08	-0.38	0.02
Steps to steady state	DPN no ulcer	6.07	2.15	0.009	1 and 2	0.80	-1.42	1.80
	DPN with ulcer	5.88	2.47		1 and 3	0.005	0.97	4.92
	Healthy	3.13	0.83		2 and 3	0.006	0.86	4.64
Distance to steady state	DPN no ulcer	1.41	1.07	0.16	1 and 2	0.50	-0.48	0.96
	DPN with ulcer	1.10	0.85		1 and 3	0.19	-1.46	0.30
	Healthy	1.90	0.93		2 and 3	0.05	-1.67	0.00
Stride length, m	DPN no ulcer	1.05	0.26	0.17	1 and 2	0.76	-0.18	0.13
	DPN with ulcer	1.06	0.16		1 and 3	0.076	-0.36	0.01
	Healthy	1.20	0.16		2 and 3	0.10	-0.33	0.03
Gait cycle time, s	DPN no ulcer	1.38	0.26	0.5	1 and 2	0.42	-0.10	0.24
	DPN with ulcer	1.31	0.17		1 and 3	0.26	-0.09	0.34
	Healthy	1.26	0.29		2 and 3	0.61	-0.15	0.25
Double stance, %	DPN no ulcer	26.83	6.90	0.13	1 and 2	0.05	0.00	8.98
	DPN with ulcer	22.64	4.81		1 and 3	0.14	-1.49	9.63
	Healthy	23.09	6.31		2 and 3	0.88	-5.70	4.96
COM, degree ²	DPN no ulcer	24.35	33.5	0.30	1 and 2	0.13	-3.98	29.11
	DPN with ulcer	14.1	6.58		1 and 3	0.67	-16.00	24.52
	Healthy	23.14	14.36		2 and 3	0.39	-27.76	11.15
CV (stride velocity), %	DPN no ulcer	9.30	7.17	0.03	1 and 2	0.15	-1.15	7.17
	DPN with ulcer	6.91	4.96		1 and 3	0.01	1.78	11.98
	Healthy	3.26	2.58		2 and 3	0.11	-1.02	8.76
Knee range of motion, degree	DPN no ulcer	50.60	9.13	0.003	1 and 2	0.30	-4.54	14.02
	DPN with ulcer	45.98	8.99		1 and 3	0.01	-26.26	-3.52
	Healthy	65.65	20.69		2 and 3	<0.001	-30.54	-8.71

^a Group 1, DPN no ulcer; group 2, DPN with ulcer; group 3, healthy control. Boldface items indicate statistical significance.

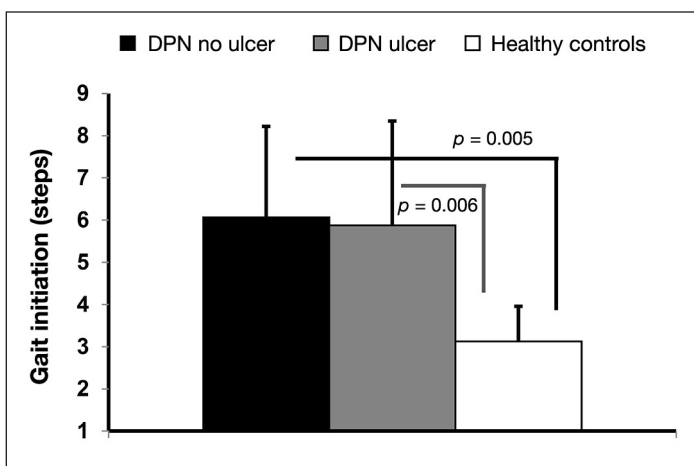


Figure 1. Between-group comparison of number of steps required to reach steady-state gait.

Knee range of motion was significantly reduced in DPN by 23% and further by 9% in DPN with ulcer compared with healthy individuals. Pairwise comparison revealed significant difference between the DPN with ulcer group and the healthy group with values of $45.98^\circ \pm 8.99^\circ$ and $65.65^\circ \pm 20.69^\circ$, respectively.

Significant group differences were observed for changes in CV for stride velocity ($p = .03$). Again, we observed a lower value of CV in the DPN with ulcer group compared with the DPN without ulcer group, with values ranging from $6.91\% \pm 4.96\%$ and $9.30\% \pm 7.17\%$, respectively (Figure 2). Between-group significance was only observed between the DPN group and the healthy group ($p = .01$). Other gait parameters did not reach the significance level ($p > .15$).

Steady-State Gait

Among various tested parameters, DS percentage ($p = .04$), COM area of sway ($p = .02$), CV in stride velocity ($p = .06$), and knee range of motion ($p = .003$) were significantly different between groups (Table 2).

Similar to the gait initiation phase, it seems that the presence of DPN reduces knee range of motion by 23% on average compared with healthy controls, and active ulcer causes a further reduction by 8.3%. Between-group difference achieved statistical significance level between DPN with active ulcer and healthy control ($67.0^\circ \pm 20.4^\circ$ in healthy versus $47.4^\circ \pm 9.6^\circ$; $p < .01$; 95% confidence interval -30.5° to -8.7°) despite nonsignificant difference for stride velocity ($p = .15$).

Double support in diabetes without foot ulcer was 26% higher than in healthy controls ($26.3\% \pm 6.9\%$ in DPN without ulcer versus $20.8\% \pm 4.9\%$ in healthy controls; $p = .02$; 95% confidence interval 0.66% to 11.09%; Figure 3). Interestingly, DS was also longer in the DPN without

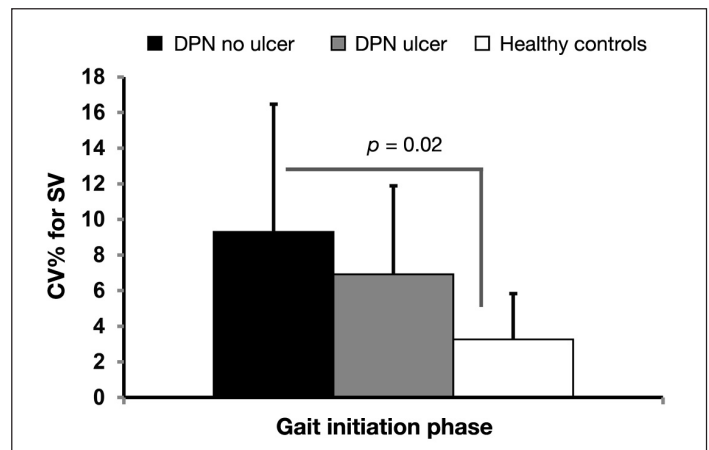


Figure 2. Coefficient of variation for stride velocity during gait initiation phase for the three groups. SV, stride velocity.

Table 2. Between-Group Comparison during Steady-State Gait Phase ^a								
Parameter	Group	Mean	SD	p value	Groups	Pairwise	95% confidence interval for difference	
Stride velocity, m/s	DPN no ulcer	0.86	0.29	0.24	1 and 2	0.82	-0.20	0.16
	DPN with ulcer	0.87	0.19		1 and 3	0.12	-0.39	0.04
	Healthy	1.02	0.19		2 and 3	0.15	-0.36	0.06
Stride length, m	DPN no ulcer	1.08	0.26	0.28	1 and 2	0.84	-0.17	0.14
	DPN with ulcer	1.08	0.17		1 and 3	0.14	-0.34	0.05
	Healthy	1.20	0.16		2 and 3	0.17	-0.31	0.06
Gait cycle time, s	DPN no ulcer	1.34	0.26	0.34	1 and 2	0.42	-0.10	0.23
	DPN with ulcer	1.27	0.16		1 and 3	0.15	-0.05	0.34
	Healthy	1.19	0.20		2 and 3	0.40	-0.11	0.27
DS, %	DPN no ulcer	26.3	6.88	0.04	1 and 2	0.03	0.28	8.80
	DPN with ulcer	22.1	4.59		1 and 3	0.02	0.66	11.09
	Healthy	20.8	4.9		2 and 3	0.59	-3.67	6.34
COM, degree ²	DPN no ulcer	15.88	7.23	0.02	1 and 2	0.39	-3.79	9.42
	DPN with ulcer	12.91	6.16		1 and 3	0.039	-16.65	-0.46
	Healthy	24.23	14.26		2 and 3	0.005	-19.14	-3.95
CV (stride velocity), %	DPN no ulcer	6.0	5.6	0.06	1 and 2	0.20	-1.19	5.34
	DPN with ulcer	4.4	4.1		1 and 3	0.02	0.72	8.71
	Healthy	1.9	1.0		2 and 3	0.17	-1.19	6.48
Knee range of motion, degree	DPN no ulcer	51.7	8.8	0.003	1 and 2	0.34	-4.87	13.70
	DPN with ulcer	47.4	9.6		1 and 3	0.01	-26.56	-3.81
	Healthy	67.0	20.4		2 and 3	<0.01	-30.52	-8.69

^a Group 1, DPN no ulcer; group 2, DPN with ulcer; group 3, healthy control. Boldface items indicate statistical significance.

foot ulcer group compared with those with active foot ulcer ($p = .03$). Although DS was 6.3% longer in the DPN with active ulcer group compared with healthy controls, the difference was not statistically significant in our sample ($p = .59$).

Interestingly, COM sway quantified by range of motion of lower back in medial-lateral and anterior-posterior during walking was higher in healthy controls compared with DPN patients, irrespective of foot ulcer ($p = .02$), which may suggest more rigidity during walking due to DPN. Results suggest that COM sway during walking was reduced by 34% ($p = .03$) and 47% ($p = .005$) for both the DPN without and the DPN with ulcer groups, respectively, compared with healthy controls (Figure 4).

We also observed significant group differences for changes in CV for stride velocity ($p = .06$). The CV was lowest for the healthy group; however, it was very interesting to observe that CV was lower for the group with foot ulcer compared with DPN without ulcer. The CV was 215% (pairwise $p = .02$) higher in the DPN group and 130% ($p = 0.17$) higher in the foot ulcer group compared with healthy individuals.

In comparing other parameters, including stride velocity, stride length, and gait cycle time, we observed no significant group differences ($p > .24$).

Discussion

Patients with DPN have a significant deficit in the ability to perceive lower extremity proprioception.¹³ Additionally, DPN is one of the factors associated with fall risk.^{13,33} Other factors include changes in gait and balance.^{12,17,20,34,35} The purpose of this study was to compare gait-related parameters in DPN with active foot ulcers, DPN without foot ulcers, and also a group of healthy controls. Only limited clinical studies have focused on or reported comparison of gait parameters between DPN and DPN with active foot ulcers. More importantly, no studies have explored the effect of offloading footwear on gait among diabetes patients,³⁶ especially among different groups of diabetes patients. Studies have reported standing balance changes due to offloading devices, but it seems no studies so far have explored fall risk as a function of offloading devices. Previous studies on the elderly have demonstrated that there is no significant relation between regular footwear and falls,³⁷ and no studies have explored the effect of offloading devices.

In the current study, when comparing the gait initiation phase, we observed significant group difference ($p < .05$) for parameters, including number of steps required to reach steady state gait, knee range of motion, and stride velocity CV. The results demonstrate how peripheral neuropathy may affect gait and subsequently impact foot ulcer on knee joint range of motion. However, based on the observed lower stride velocity CV in the ulcer group, we speculate that the prescribed footwear may be playing an important role. We further speculate that these footwear maybe compensating for the lost sensations of the foot. Adding to our speculations, we observed that the presence of ulcer did not significantly affect stride velocity among the ulcer group, as the values were close to those of the DPN group. Previous research studies have reported that, compared with healthy individuals, velocity is significantly lower in

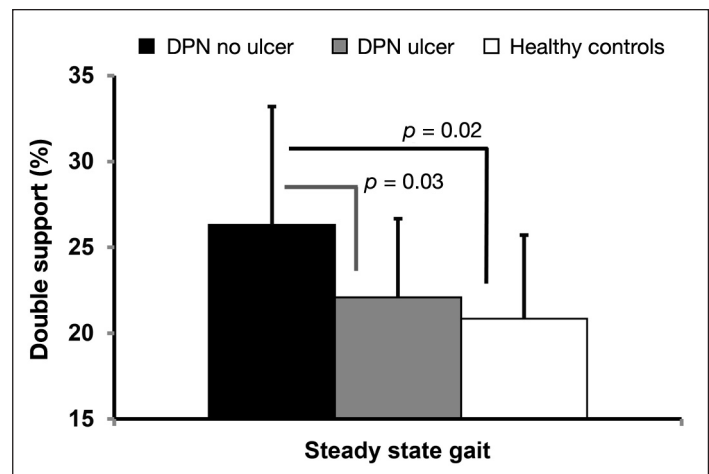


Figure 3. The DS period comparison between the three groups during steady-state gait.

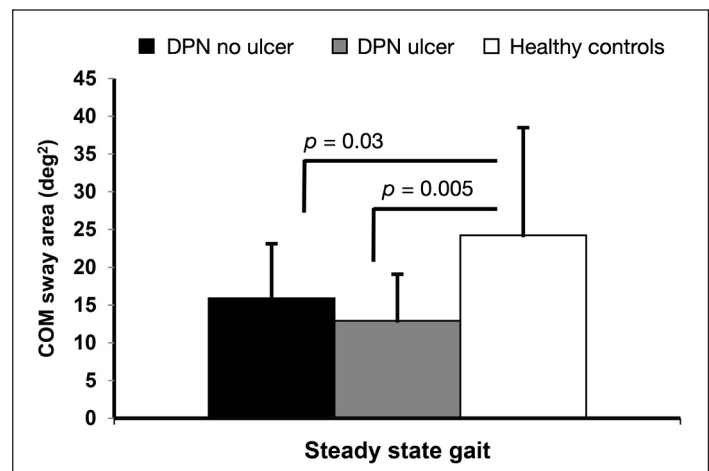


Figure 4. The COM sway area comparison between groups during steady-state gait.

DPN with history of ulcer.²² Interestingly, our results also show that DPN with ulcer has similar velocity values as DPN without ulcer.

While comparing steady-state phase of gait, we observed significant group differences for other gait parameters, including DS and COM area of motion during walking in addition to knee range of motion and stride velocity CV. The DS period did not show any group difference during gait initiation period; however, there was apparent difference during the steady-state gait, where DPN groups were significantly higher than healthy controls, as reported previously.¹⁸ However, it was observed that the DS period among DPN with active foot ulcer was lower than DPN without ulcer by 19%. The DS period observed in the current study is also comparable to previous research, which evaluated the effect of strut height on offloading capacity of removable cast contacts in moderate/high risk for ulcer patients.³⁸

Since the DS period difference was not significantly different among the three groups during gait initiation period, it suggests that, during initial gait, all the three groups may be struggling; however, after gait initiation, only healthy controls managed to bring the DS period closer to 20%. We hypothesize that, since insensate feet are one of the major causes of gait deterioration among DPN patients, in our cohort of 15 DPN subjects with an active foot ulcer, 12 wore prescribed footwear, which may have improved their foot perception from contact with the sensate skin above the ankle. On the other hand, only 7 out of 15 DPN patients without ulcer wore prescribed footwear. Improved perception of lower extremities in DPN with an active foot ulcer may have caused better gait characteristics compared with DPN patients without ulcer.

The stride velocity CV maintained significant group difference both during gait initiation and during steady-state gait. A trend of increase in CV for stride velocity was found from healthy individuals to DPN with active foot ulcer followed by DPN without ulcer. This shows that the DPN with ulcer group was better able to reduce the variations in gait, again probably because of some somatosensory feedback that they received from the footwear to the sensate skin. All these findings indicate that offloading modalities are not only helping heal ulcers more rapidly, but may also be providing secondary feedback to intact skin.

Knee joint range in the sagittal plane also showed significant groups difference during steady-state gait. Several factors are associated with a reduction of range for diabetes, including peripheral neuropathy. Also, the offloading footwear would cause restriction and reduction of joint movement. Previous studies have found significant difference in maximum knee joint angle between DPN without foot ulcer and with history of foot ulcers.²² In comparison with other studies, it should be noted that this current study recruited participants with active foot ulcers and measured range of motion as opposed to absolute value. It is very interesting to note that, even though range of motion among the DPN with ulcer group is lower than the DPN without ulcer group, still the gait seems more stable in the DPN with ulcer group based on DS period and CV in gait speed data.

The COM sway area was significantly different between groups during steady-state gait. Both DPN groups, when compared with healthy individuals, had significant difference in sway, suggesting the rigid walking pattern from limited joint motion caused from diabetes complications. The COM sway differences were evident only during steady-state gait phase.

The current study had a few limitations, including that we excluded patients with peripheral artery disease; however, we did not do any additional tests for peripheral artery disease, therefore some of the patients recruited might have peripheral artery disease. Second, we did not standardize the type of footwear; however, since our intention was to measure gait alterations in real-world scenarios, we opted for patients to wear prescribed or habitual footwear. Based on the results of this study, it seems that further research is warranted to explore the effect of prescribed footwear in ulcer patients, and perhaps also daily activity monitoring to assess changes in quality of life from the provided ulcer treatment.

Conclusions

Overall comparison of various gait parameters suggests that there is significant group difference between the three

groups: DPN without ulcer, DPN with ulcer, and healthy. Interestingly, DPN patients with active foot ulcers exhibit a slightly better gait than DPN patients without foot ulcer. We hypothesize that the type of footwear worn by DPN patients with active foot ulcers may provide a better gait and sensation from sensate skin. Previous studies have reported that, by using offloading devices, standing balance may be compromised;^{36,39} however, as far as gait related-parameters are concerned, the current study also found that variations in stride velocity and DS were lower in the DPN group with active foot ulcer wearing offloading device compared with the DPN without ulcer group. It should be pointed out that previous studies explored the effect of offloading footwear on balance among diabetes patients with foot ulcer only. Therefore, it would be beneficial to further elucidate the role of offloading devices in improving gait related-parameters, especially among the diabetes population. The possible explanation for improved gait could be enhancements in somatosensory feedback from cast via contact with sensate skin above and around the ankle joint. The results from this study also raise an interesting question to explore if the diabetes patient population wearing offloading devices is at risk of falling during gait from wearing the device.

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The statements made herein are solely the responsibility of the authors.

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