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The Effect of Custom Insoles on Muscle Activity in Diabetic Individuals with Neuropathy

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Abstract: Foot ulcers are amongst the most serious complications of diabetes. Guidelines recommend that people with diabetes wear appropriate footwear or insoles to reduce repetitive stresses. Excessive plantar pressure has been recognized as the major risk factor for plantar ulcers in diabetic individuals; custom insoles are indicated as the gold standard treatment to unload the foot structure. The aim of this study was to investigate the effect of custom insoles on biomechanical and neuromuscular functions in diabetic neuropathic individuals. Ten diabetic subjects walked with and without custom insoles at their preferred speed; ten controls were assessed for comparison. Data were captured through seven video cameras, plantar pressure insoles, and surface electromyography. The electrical activity of Rectus Femoris, Tibialis Anterior, Medius Gluteus and Gastrocnemius Lateralis were acquired bilaterally. The plantar pressure and surface electromyographic variables were determined, while videos were used to detect the gait cycle. The following comparisons were made across the variables through the non-parametric SPM1D test ($p < 0.05$): condition with vs. without insoles vs. controls. Custom insoles provided a reduction in plantar pressure through contact surface redistribution in association with a reduced electromyographic activity. Our results suggest optimizing the prevention approach by including personalized foot and ankle exercises.

Keywords: custom insole; plantar pressure; surface electromyography; diabetic neuropathy; gait analysis

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1. Introduction

Diabetes is a chronic, metabolic disease affecting about 422 million people worldwide and about 1.5 million deaths are directly attributed to diabetes each year [1]. Diabetes is characterized by elevated levels of blood glucose which over time leads to serious damage to the heart, blood vessels, eyes, kidneys, and nerves [1]. Type 2 diabetes mellitus individuals are at increased risk for multiple and complex morbidities related to macrovascular disease (e.g., coronary heart disease, stroke, and peripheral arterial disease) and microvascular disease (e.g., nephropathy, retinopathy, and neuropathy) [1]. After 10 years of disease duration, up to 50% of individuals with type 2 diabetes mellitus develop diabetic peripheral neuropathy (PN), a major risk factor for diabetic foot related problems [1,2]. The second major risk factor is peripheral arterial disease, and both are extremely common in elderly patients. The estimated prevalence of peripheral arterial disease is 60.6% in individuals aged ≥70 (mean age 78 years), while the prevalence of PN can be as high as 35% in adults aged ≥80. It has been estimated that every 30 s a lower limb is lost somewhere in the world as a consequence of type 2 diabetes mellitus [3–5]. It is expected that 19 to 34% of diabetic individuals will develop an ulcer, and it is well known that ulcers precede 80% of all diabetic lower limb amputations [6]. The pathways to ulceration are similar in most cases and affect individuals with diabetes and simultaneously two or more risk factors. Within PN, sensory neuropathy results in the loss of the body's protective feedback mechanism, and motor neuropathy can affect balance and spatial awareness; while autonomic neuropathy contributes to skin becoming dry and thin and

more susceptible to damage [7]. All these dysfunctions contribute to the reduced tissue perfusion that causes a reduction in tissue oxygenation, and may result in an increased vulnerability to mechanical stresses. Furthermore, changes in the foot structure, the rigidity of the connective tissue, and the loss of foot and ankle muscle volume and strength are all recognized as being responsible for abnormal ground reaction forces during gait, the major cause of friction or pressure-related lesions (i.e., callus, corns, blisters, abrasions) [8]. On the other hand, peripheral arterial disease is a progressive disease caused by atherosclerosis that leads to the ischemia of the lower limb tissue and promotes the development of ulcers. People with diabetes have four times the risk of PAD than people without diabetes. The typical symptoms are intermittent claudication, characterized by the cramping pain in legs after short walks which results in altered spatiotemporal gait parameters such as decreased step length, cadence, and velocity [9]. Both PN and peripheral arterial disease are known to be responsible for changes in gait biomechanics and specifically for causing alterations in plantar pressure, lower limb joint kinematics, ground reaction forces, and muscle activity [8–15]. Recently, physical exercise programs focused on gait training through strengthening, stretching, and balancing have shown positive results towards the prevention of foot ulcers, amputation, and fall risk [16]. However, the crucial factor in diabetic foot prevention remains the increase in pressure and shear forces, related to changes in foot structure, which produces hyperkeratosis presenting as callus. For instance, areas of plantar callus are commonly seen when the pressures relating to gait and footwear are abnormal [7]. If the pressure on the affected area of the skin and the subsequent callus that develops are not relieved (i.e., offloading and/or mechanical debridement), localized trauma to the tissues are generated [7]. Approximately 50% of diabetic foot ulcers occur on the plantar aspect of the foot and can progress into chronic and non-healing ulcers if not treated appropriately [17]. Offloading is one of the crucial aspects of the treatment aiming to redistribute pressure away from the ulcer site [18], to reduce further tissue trauma, and to facilitate the wound healing process [17–19]. It can be achieved through casting, footwear, surgical interventions [20], shoe modifications, orthotic walkers, and other offloading techniques [21,22]. In particular, Lin et al. demonstrated that forefoot plantar pressure can be reduced by removing plugs and adding arch support to foam-based insoles in PN individuals [20]. With this said, the most common outcome measures to determine the neuromuscular and biomechanical effects of foot orthosis or insoles are lower limb kinematics, kinetics, plantar pressure, and surface electromyography (sEMG) [23–25], of which plantar pressure is the most commonly used [26,27]. On the side of these more common measures, finite element modelling [28,29] and ergonomic evaluations [30] have been applied to plan and test the effects of different insoles, not only on diabetic foot individuals, but also on healthy subjects. In the latter case, comfort assessment questionnaires were adopted to complement the electromyographic and plantar pressure measures [30]. In this scenario, to the best of the authors' knowledge, no previous studies investigated the effect of custom insoles on PN individuals by combining dynamic plantar pressure with surface electromyography during gait. Based on this evidence, the aim of this study was to investigate whether the biomechanical effects of Custom Insole (CI), measured in terms of dynamic plantar pressure and ground reactions forces, are associated with the neuromuscular effects, in terms of sEMG, in subjects at risk of diabetic foot.

2. Materials and Methods

2.1. Population

Ten PN subjects and ten age-matched healthy controls (C) have been enrolled in this study (anamnestic data were reported in Table 1). Inclusion criteria for PN individuals were: type 2 diabetic subjects with PN, the ability to walk autonomously, no history of ulcers or neurological disorders, and no history of orthopedic problems other than diabetes-related lower limb surgery or cardiovascular disease. The inclusion criteria for C were: the ability to walk autonomously, the absence of neurological disorders and orthopedic problems, lower limb surgery, or cardiovascular disease. The Risk Score was assessed for

each diabetic subject according to the International Diabetes Federation guidelines [3] (see Table 1). Power analyses [31] (considering the mean values of the peak of the envelopes from previously published data [11]), indicated that three to ten participants per group were necessary to compare subjects with PN and C. We therefore enrolled ten subjects for each group. The following equations were applied as in [31]:

$$n = \frac{2}{d^2} \times c_{p,power}$$

$$n = \frac{2}{0.78^2} \times c_{0.05,80\%}$$

$$N' = \frac{N(1+k)^2}{4k}$$

where n is the number of subjects required in the group, d is the standardized difference and $c_{p,power}$ is a constant defined by the values chosen for the p value and power.

Table 1. Anamnestic data: PN = Peripheral Neuropathy, C = healthy controls, Risk classification according to [3], N.a = not available, * = $p < 0.05$.

	Age (Mean ± st.dev)	Weight (Mean ± st.dev)	Height (Mean ± st.dev)	BMI (Mean ± st.dev)	Risk Classification [3]			Years of Disease
					1	2	3	
PN	61.7 (±12)	93 (±20) *	1.73 (0.07)	30 (±5) *	80%	10%	10%	27.6 (±13)
C	61.2 (±5.07)	70 (±17)	1.68 (12)	24 (±3)	N.a			N.a

2.2. Acquisition Set Up

Subjects walked while wearing (CI) and not wearing (NoCI) the CI at their preferred walking speed at the orthotics manufacturer site (Figure 1); a minimum of three walking trials per subject were collected through seven video cameras (GoProHero 7®), plantar pressure insoles (Novel PedarX system, 99 sensors per insoles, 20.000 sensors/second), and an sEMG system (FREE EMG1000, 1000 Hz, BTS). The electrical activity of four muscles was simultaneously acquired bilaterally: Rectus Femoris (RF), Tibialis Anterior (TA), Medius Gluteus (MG), Gastrocnemius Lateralis (GL). After appropriately cleaning and preparing the skin, sEMG electrodes were placed according to the guidelines reported in [32] (Figure 2). The sensors (Hydrogel/Ag/AgCl, Kendall Arbo H124SG, Covidien, Dublin, Ireland) were 24 mm in diameter and positioned 1 cm apart. Retroreflective markers were applied bilaterally on calcaneus, lateral and medial malleolus, first, second and fifth metatarsal heads, tibial tuberosity, and the head of the fibula. The same evaluators recorded the data (the first author recorded the sEMG signals, the third author recorded the video and pressure data) of all participants. The present study was approved by the Ethics Committee of the Padua University Clinics (N°1001P). Each subject signed the informed consent form.

Figure 1. Example of acquisition set up.

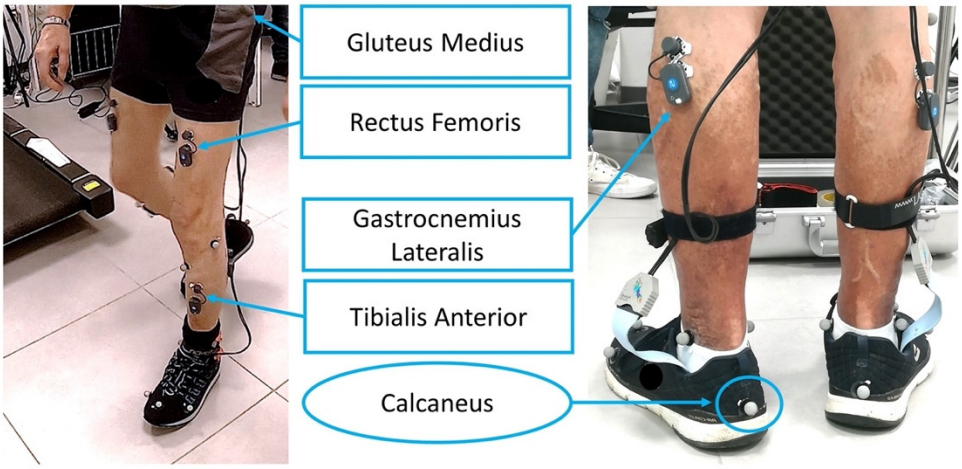


Figure 2. Details of sEMG probes location.

2.3. Custom Insoles

Details of CI are reported in Table 2.

Table 2. Technical details of CI.

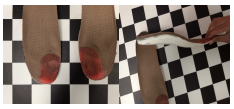
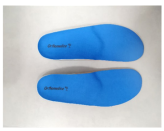
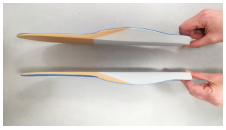
Subject	Prescription	Production Method	Insole Material	Insole Cover Material	Insole Shape	Produced Insole Picture
1	custom with arch supports	CAD/CAM	Biomech mt197	Diapod	Ecosanit	
2	custom, multilayer	casting	POD 50 + stress balance under the hallux + heel rigid reinforcement in Duroform	PPT perforated	Ecosanit	
3	custom, total contact	CAD/CAM	Orthoshock	Drypod	Normal	
4	custom with medial arch support, supination heel wedge	CAD/CAM	Orthoextreme 35sh	Diapod	Normal	
5	custom, casting unloaded, unload 1st right toe, wrap heel, toe support left	casting	Pod 50 + sunfiber	Diapod	Ecosanit	
6	custom with insole with reinforcement base	CAD/CAM	Pod 50	Diapod	Ecosanit	
7		casting	Pod 50 + sunfiber	Diapod	Ecosanit	

Table 2. *Cont.*

Subject	Prescription	Production Method	Insole Material	Insole Cover Material	Insole Shape	Produced Insole Picture
8	custom	casting	Pod 50	Diapod	Ecosanit	
9	custom, wrapping, with right heel discharge and lateral wedge	casting	Pod 50	Diapod	Ecosanit	
10	custom with plantar arch support	casting	Pod 50	Diapod	Ecosanit	

2.4. Data Analysis

The sEMG-recorded signals were bandpass filtered between 10 Hz and 450 Hz with a 5th order Butterworth filter and full wave rectified. The envelope was computed by low-pass filtering the signals with a 4th order Butterworth filter and a cut off frequency of 5 Hz. sEMG signal envelopes were computed and normalized to the maximum value within the 3 gait cycles [33]. The following parameters were determined from the plantar pressure insoles: peak and mean pressure, the vertical component of the ground reaction force (GRF), the center of pressure (COP) displacement in the anterior–posterior and medial–lateral directions, and contact surface. Peak and mean pressure were normalized with respect to body weight (%BW) and with respect to BW and contact surface (%BW·mm^2), GRF with respect to BW (%BW), and COP displacement with respect to the plantar pressure insole length in anterior–posterior and medial–lateral directions. All data, except for the COP, were filtered using a 3rd order lowpass Butterworth filter with a cutoff frequency of 1/8 of the sampling frequency [34]. The video sequences were processed in order to extract the three dimensional heel and first metatarsal head landmark coordinates through the software "Track on Field" (BBSoF S.r.l.). Gait cycles were defined by combining the plantar pressure data with both the heel and the first metatarsal head marker trajectories. All analyses were performed in Matlab R2021b.

2.5. Statistical Analysis

The anamnestic data (i.e., age, height, weight, and BMI; see Table 1) between the two populations were compared through a Wilcoxon Signed Rank Test ($p < 0.05$). The comparison among PN, with and without CI, and C, was carried out through the non-parametric 1D statistical parametric mapping (SPM1D) [35]. SPM1D's non-parametric procedures were calculated for each time node and were expressed as SPM1D{t} trajectories. A critical threshold was then defined that only 5% ($\alpha = 0.05$) of identically smooth random curves were expected to exceed. Parts of the gait cycle where the SPM1D{t} trajectory crossed this threshold were identified as clusters with a significant outcome, for which cluster-specific p-values were calculated based on the random field theory [36]; Bonferroni correction for multiple testing brought α to 0.017. All SPM1D analyses were performed using the spm1d open source code (vM.0.4.5, http://www.spm1d.org, accessed on 27 November 2019) in MATLAB®. The data of the right and left side were considered together as no statistically significant differences were detected (SPM1D non-parametric paired).

3. Results

3.1. Comparison with Healthy Subjects

In terms of demographic parameters, the PN subjects showed statistically significantly higher weight and BMI (* $p < 0.05$ see Table 1). In terms of sEMG activity (Figure 3), statistically significant differences were observed either in the condition with or without CI. Overall, the envelope profiles of PN subjects showed an altered pattern throughout the gait cycle. Specifically, at the level of TA, in NoCI condition, a statistically significant reduction was observed during swing, while a statistically significant increase was detected during both midstance and terminal stance. In the CI condition we observed a reduction of TA activity at loading response and initial swing accompanied by an increase of activity at terminal stance. When we consider the GL in the NoCI condition, a statistically significant increase of activity was observed from the push off phase up to terminal swing. In the CI condition a statistically significant decrease was observed at the end of the midstance, accompanied by an increase during the midswing. In terms of RF in the NoCI condition, a statistically significant decrease was noted at loading response, accompanied by a statistically significant increase from the midstance up to the end of the gait cycle. In CI condition RF showed a statistically significant decrease from loading response up to midstance, followed by a statistically significant increase during the midswing. Finally, the GM in the NoCI condition showed a statistically significant decrease at loading response followed by a statistically significant increase from the midstance up to the end of the gait cycle. In the CI condition a similar trend was observed.

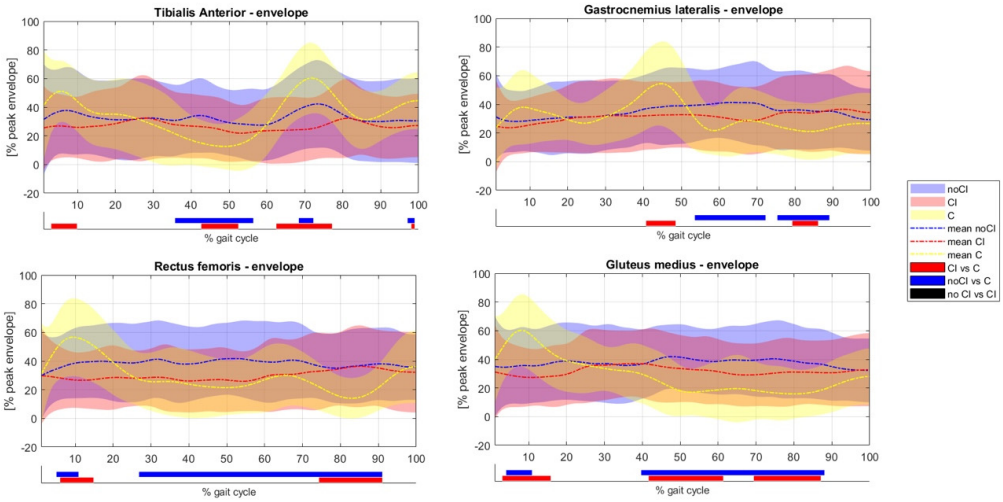


Figure 3. Variables extracted from sEMG signals. From top to bottom, from left to right: mean and standard deviation of the sEMG envelope (Mean value = dashed line, mean ± 1 standard deviation = shaded area) of Tibialis Anterior, Gastrocnemius Lateralis, Rectus Femoris, Gluteus Medius. In yellow, the sEMG values of the control subjects (C); in blue, that of the PN subjects without wearing the custom insole (NoCI); and in red, that of the PN subjects while wearing the custom insole (CI). On the y axis, the envelope values normalized on the peak value detected during gait (% peak envelope), on the x axis, the gait cycle percentages. At the bottom of each figure: blue bars indicate the instant of the gait cycle where statistically significant differences were detected between C and NoCI; red bars indicate the instant of the gait cycle where statistically significant differences were detected between C and CI; and green bars indicate the instant of the gait cycle where statistically significant differences were detected between NoCI vs. CI ($p < 0.05$).

Overall, in terms of dynamic plantar pressure (Figure 4), a statistically significant increase was observed on both mean and peak pressure, with and without the CI, for the majority of the stance phase of gait. However, a statistically significant reduction in the CI condition was observed with respect to NoCI. To detail, when considering the normalized peak pressure in the CI condition, a statistically significant reduction can be observed with

respect to C from initial contact up to loading response, and from midstance up to pushoff. It is worth noting that in the NoCI condition, for the normalized values, a statistically significant decrease was detected at initial contact and from terminal stance up to pushoff, while an increase was recorded during midstance, in contrast to the CI assessment. In terms of GRFs, overall, statistically significant lower values were detected in both the CI and NoCI conditions, with the exception of 10% of the stance phase of gait, where an increase was noted (i.e., 40–50%). Overall, the contact surface recorded higher values during the all-stance phase of the gait in the CI condition. Finally, in terms of medial–lateral and anterior–posterior COP displacement in the CI condition, PN subjects showed a statistically significant higher displacement in the medial direction and lower in the anterior direction, when compared with C.

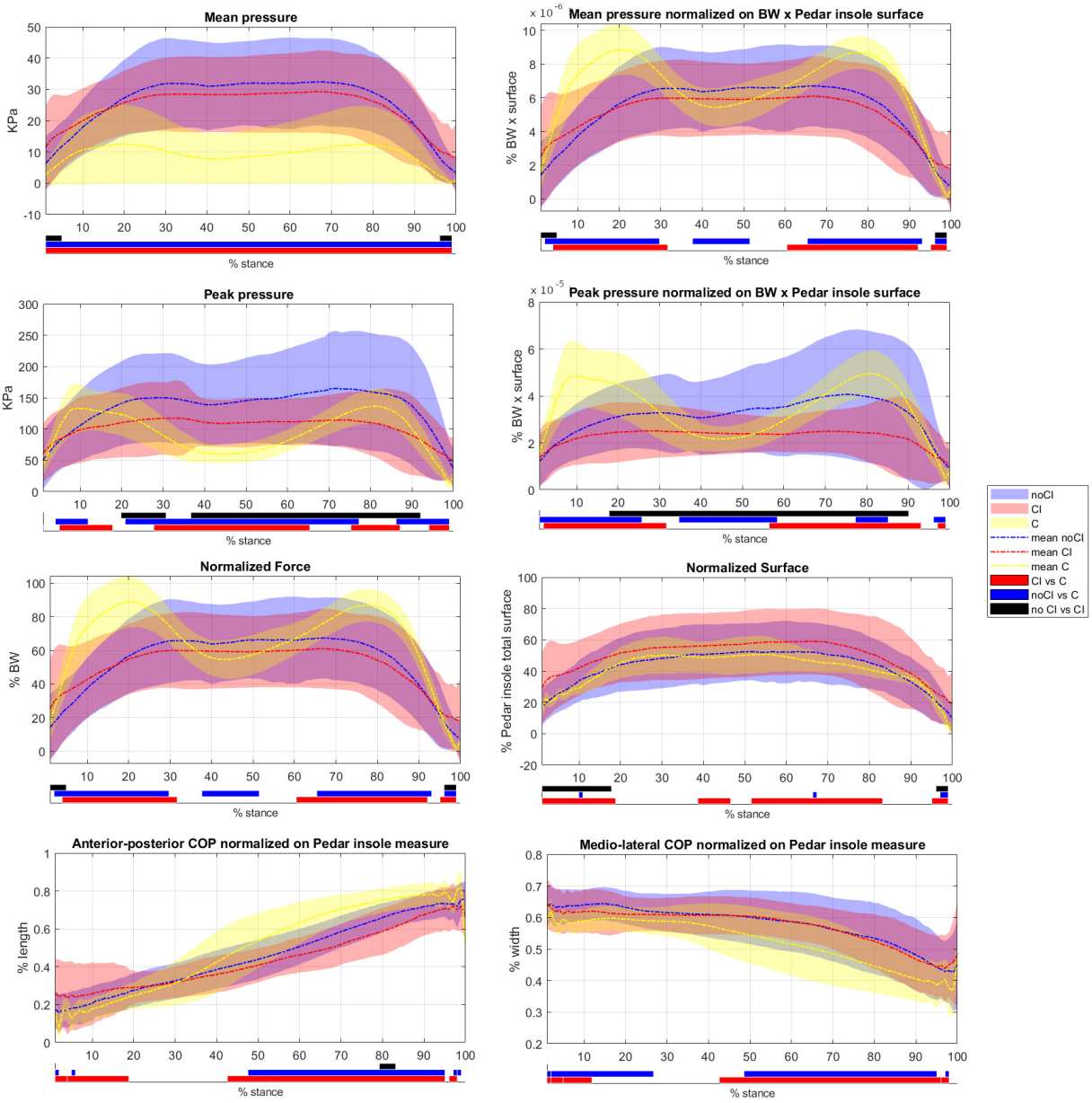


Figure 4. Plantar pressure variables. From top to bottom and from left to right: mean pressure in KPa and mean pressure normalized on body weight (BW) and surface of the plantar pressure insole (%BW*Surface); peak pressure in KPa and normalized peak pressure %BW*Surface; ground reaction

force (GRF) normalized on BW (%BW); surface normalized on the total surface of the plantar pressure insole (%Surface); the centre of pressure (COP) displacement normalized on the total surface of the plantar pressure insole in medial-lateral and anterior–posterior directions All results are represented as bands (mean value = dashed line, mean ± 1 standard deviation = shaded area). On the y axis are the units, and on the x axis, the stance phase of the gait cycle percentages. In blue, the data of the PN subjects without wearing the custom insole (NoCI); in red, the data of the PN subjects while wearing the custom insole; and in yellow, the data of the healthy controls (C). At the bottom of each figure: blue bars indicate the instant of the gait cycle where statistically significant differences were detected between C and NoCI; red bars indicate the instant of the gait cycle where statistically significant differences were detected between C and CI; green bars indicate the instant of the gait cycle where statistically significant differences were detected between NoCI and CI ($p < 0.05$).

3.2. Comparison between CI and NoCI Conditions

In terms of sEMG activity (Figure 3), an overall reduction was detected on each muscle in the CI condition, though this was not significant. In terms of dynamic plantar pressure (Figure 4), a statistically significant decrease was observed for the majority of the stance phase in the CI condition, associated with an increase in the plantar surface. An exception can be found in both mean pressure and GRFs at both the beginning (0–10%) and the end (98–100%) of the stance phase of gait, where a significant increase was detected.

4. Discussion

There is a general consensus [3] on adopting various offloading techniques (i.e., casting, specific footwear, plantar orthotics, and surgical interventions such as callus debridement) to prevent foot ulcers in patients with diabetes. CIs in particular are among the most commonly used approaches to treat or prevent diabetic foot pathology [22]. CIs have been proven to provide a beneficial effect by reducing localized excessive mechanical stresses [37–40] and promoting a load redistribution on the plantar aspect of the foot, thus reducing the soft tissue strain [39]. In particular there is an agreement on the consideration of custom therapeutic insoles as being more effective than over-the-counter insoles in diabetic foot prevention [22]. The standard methodology for assessing the efficacy of CIs is through kinetic measurements [6,38,41,42] with mean pressure, peak pressure, pressure–time integral and force–time integral as the most frequently used parameters [6]. In agreement with previous studies, our results showed a reduction in peak pressure through a redistribution of contact surface (i.e., increased contact surface was registered in our sample subject) in the CI condition. However, reducing high plantar loads or foot pressures should not be considered a standalone mechanism. There is agreement in the literature that PN generates functional gait variations related to the altered lower limb joint range of movement, reduced active muscle power, reductions in spatiotemporal parameters, increased kinetics (i.e., GRFs and joint moments), and altered EMG [43]. Although it has been demonstrated that in PN subjects an altered dynamic plantar pressure might be the result (or might be the cause) of altered muscle activity, there is limited research data on the assessment of the effect of CIs on PN subjects' sEMG. The aim of this study was to investigate if the biomechanical effects of CIs (measured in terms of dynamic plantar pressure, GRFs, and COP displacement) were associated with the neuromuscular effects (assessed in terms of muscular function) in subjects at risk of diabetic foot. In respect to this aim, our results indicated a reduction in the activity of the lower limb distal muscles. TA sEMG activity in particular was reduced at loading response and between pushoff and initial swing, which are the phases wherein muscles should provide the necessary support to the plantar surface in order to reduce the impact with the ground. The results were similar for GL, but only for what concerns terminal stance. At the level of proximal muscles, a reduction has been observed on the RF from loading response up to midstance, similarly to what is detected on the GM, again confirming a reduction in the support provided by the muscles during the landing phase. Our results demonstrate agreement with the current literature reporting muscle weakness and atrophy of the lower limbs as a consequence of

PN [43–45], which is further exacerbated when sarcopenia is present. This has also been reported in association with a reduction of maximum voluntary isometric contractions and a reduced number of motor units recruitment [46]. These characteristic alterations have also been documented in terms of decreased flexor and extensor concentric torque at the knee and ankle joints in people with type 2 diabetes with more severe PN [47,48]. With that said, recently, the inclusion of rehabilitation approaches such as foot and ankle exercises have been suggested as preventive strategies for diabetic foot individuals. In this respect, the following foot-related outcomes were indicated: an increased nerve velocity conduction of the lower limbs, skin sensitivity and intraepidermal nerve fiber density, delayed skin damage and ulceration [49], and improved foot–ankle range of motion and PN symptoms [50]. Furthermore, a positive impact on muscle weakness, foot deformities, the rigidity of connective tissue, poor balance, foot rollover, dynamic plantar pressure distribution, and coordination have been detected [51]. Detailed guidelines are available for prescribing custom foot orthotics and insoles with the aim of reducing excessive tissue mechanical stress and consequently the plantar ulcers. However, no specific indications can be found regarding the prescription of foot and ankle exercises as part of the preventative treatment [16]. Within this scenario, our results, which detected a reduction of lower limb muscle activity with and without CIs, seem to indicate the need to consider muscle function when planning plantar insoles in the presence of PN. A similar approach has been successfully adopted to reduce lower limb and back discomfort in assembly line workers in a rubber tire factory [52]. Our study has some limitations that should be acknowledged: the small sample size, which prevents our findings from possible generalization; the heterogeneity in the CI material, that could be a confounding factor and may indicate the need for a larger study exploring the relationship between CI materials and sEMG; to best of our knowledge, no previous studies have investigated the effect of CI on PN subjects through sEMG analysis, therefore no possible direct comparisons with our findings can be conducted; in terms of sEMG analysis, other parameters could have been extracted such as timing, frequency, and duration of muscle activity [13,44]; however, our approach (i.e., sEMG envelope analysis) has been successfully adopted with similar purposes in a different pathology [53]; the high variability of gait documented in diabetic individuals could have exacerbated the subjectivity in responding to foot orthoses and footwear [54].

5. Conclusions

The literature concerning the assessment of CI efficacy in pathologies other than diabetic foot has already reported measures of the effects of CI both in terms of mechanical and neuromuscular factors [23]. In particular, lower limb joint kinematics and kinetics, ground reaction forces, dynamic plantar pressure, and sEMG are the more frequently reported [23]. By considering the complex impact of PN on the musculoskeletal system, and on diabetic foot ulcers in particular, our findings, though preliminary, seem to support the inclusion of muscle activity measures in the prescription of plantar insoles. This consequently supports the inclusion of foot and ankle exercises in the prevention pathway as beneficial. With this in mind, some future developments can be considered: first, an increase of the sample size; second, the combination of the prescription of CIs with personalized foot and ankle exercises; and finally, the investigation of CI impact on gait kinematics.

Author Contributions: Conceptualization, Z.S. and F.S.; methodology, Z.S., F.S., A.G. and A.C.; software, A.C. and A.G.; formal analysis, A.C., A.G. and F.S.; investigation, Z.S.; data curation, F.S., A.G. and A.C.; writing—original draft preparation, Z.S. and F.S.; writing—review and editing, Z.S. and F.S.; visualization, Z.S.; supervision, Z.S.; project administration, Z.S. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of the Padua University Clinics (N°1001P). Each subject has signed the informed consent.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets for this study will be available upon request to interested researchers.

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Conflicts of Interest: The authors declare no conflict of interest.

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