Effects of Total Contact Orthosis on the Plantar Pressure during Walking Activities for Diabetic Foot

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I hereby certify that this work has not been accepted in substance for any other degree, and is not being currently submitted in candidature for any degree.

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Abstract

Abnormal plantar pressures during different walking activities cause an adverse effect on the plantar load distribution in people with diabetic foot complications. However, limited data are available to examine the plantar peak pressure during different walking activities in diabetic people. The aim of this study was to investigate the plantar pressure from four regions of the foot during different walking activities (i.e., level walking, ramp ascending, ramp descending, stair ascending and stair descending) in neuropathic diabetic subjects without and with a total-contact orthosis (TCO). Sixteen neuropathic diabetic subjects aged 40-60 years with calluses and foot deformities were included in this study and were provided with a TCO made up of multifoam, Plastazote® and microcellular rubber. Peak plantar pressure and contact area without a TCO and with a TCO were recorded using the Pedar X® system during different walking activities. With the TCO significant reduction of peak plantar pressure at toes and forefoot when compared without TCO during different walking activities. Peak plantar pressure increased at the midfoot region when walking with a TCO and no significant difference was observed at the hindfoot region between two conditions. Furthermore, contact area was increased during level walking with a TCO compared to other walking activities. The reduction and redistribution of the peak plantar pressure occur with the use of TCO from the site where the ulceration rate is higher as at the toes and forefoot compared to the other regions of the foot.

Keywords: Diabetic foot, Total contact orthosis, Biomechanics, Plantar pressure, Ulceration, Walking activities

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Contents

List of Table

List of Figures

List of papers and proceeding

1. **Muhammad Nouman**, Wipawan Leelasamran, and Surapong Chatpun. Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities **(Submitted)**

2. **Muhammad Nouman**, and Surapong Chatpun. The Role of Total Contact Orthosis on Plantar Pressure Distribution during Stair Walking in People with Diabetes. The 30th Conference of The Mechanical Engineering Network of Thailand 5^{th}-8^{th} July 2016, Songkhla, Thailand **(Conference proceeding)**

Submitted manuscript was accepted by Foot & Ankle International

11-Mar-2017

Dear Author:

It is a pleasure to accept your manuscript entitled "Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities" in its current form for publication in Foot & Ankle International.

Thank you for your fine contribution. On behalf of the Editors of Foot & Ankle International, we look forward to your continued contributions to the Journal.

Sincerely,
David B. Thordarson, MD
Editor-in-Chief, Foot & Ankle International
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1. Introduction

The long-term complication for the diabetic patient is foot ulceration and re-ulceration (1). The lifetime risk for ulceration of diabetic foot is 25% (2). It is estimated that 80% of diabetic patient with ulcers have neuropathy, which provokes ulceration resulted from decreased pain sensation and perception of plantar pressure (3). Elevated plantar pressure is considered to be the most frequent cause of ulceration in the presence of neuropathy and foot deformities (4-8). Prolong foot complication with ulceration lead to minor or major amputation. Diabetic foot ulceration and amputation are dreadful complications linked to diabetic neuropathy, where it affects directly the individual both socially and economically (1, 9-12) . Foot deformities results in an abnormal gait pattern and neuropathy in addition causes an abnormal prolong pressure under the metatarsal heads where high rate of ulceration found (3, 13). Even an ulcer heal with medical therapy the chances of having re-ulceration is still as high as 17%-60% (13). It is the repetitive dynamic peak plantar pressure at a specific site that causes re-ulceration (7). Callus formation is a precursor to ulcers formation, as callus formation under bony prominences is caused by the friction between the footwear and the foot (14-16). The callus under the metatarsal heads increases the plantar pressure leading to break down of the skin (17). The protection is only possible with use of appropriate footwear and foot orthosis where it redistributes the peak plantar pressure from high pressure to low region area of the foot (5, 15, 18, 19). Information regarding the plantar pressure is important for identification of various foot pathologies. Both diabetic shoes and foot orthotics have a positive effect on offloading the peak plantar pressure (15). It is reported that high plantar pressure can be reduced effectively through the use of total contact orthosis as it accommodates the foot with deformities results in redistribution. Plantar pressure can be measured with in-shoe systems, which reveal interaction between foot and footwear during different activities (20, 21). Several studies compared the pressure distribution of a custom made insole and prefabricated insole (22). The custom made insole was considerably better when compare with the prefabricated insole in terms of pressure distribution and contact area (23). Activities affect the plantar pressure distribution, as researchers compared level walking with the stair walking and found different results (24, 25). Some found lower plantar pressure at the heel; however others found lower plantar pressure at hallux. During level walking big toe, 3^{rd} metatarsal head and heel experienced high plantar pressure, whereas 2^{nd}, 3^{rd} metatarsal heads and big toe are identified as regions with high plantar pressure during stair walking (ascending and descending) (26-28). There is still limited information regarding different walking activities and the effectiveness of total contact orthosis. With an understanding of specific activity and the regions of the foot where high plantar pressure occurs, the load distribution can be managed well with the total contact orthosis. A positive approach towards management of diabetic foot ulceration can reduce the number of lower limb amputation and foot complications.

2. Objectives

The objective of this study was to investigate the plantar pressure at four regions of the foot during different walking activities (i.e. level walking, ramp ascending, ramp descending, stair ascending and stair descending) in diabetic neuropathic subjects without and with total contact orthosis.

3. Materials and methods

3.1 Subject selection

Sixteen diabetic subjects participated in the study (Male =9, female = 7). The participants were included if their age range from 40-60 years with type II diabetes, history of callus at forefoot or hindfoot at the time of evaluation or having forefoot deformity. Forefoot deformities include hammer toe (contracture of proximal interphalangeal joint of 2nd, 3rd and 4th toes), mallet toe (fixed distal interphalangeal joint of toes) and hallux valgus (big toe deviation towards lateral side of the foot). The blood pressure should not exceed 140/90 mmHg, having insensate or diminished sensation noted with a 10 g monofilament and able to walk independently at least 10 m at a self-selected speed. Potential subjects were excluded if there was foot ulcerations, joint surgery of lower limb or the presence of an unhealed open wound at the time of the experiment, a partial or total amputation, ischemic heart disease or unable to understand the simple instructions given during the study protocol.

3.2 Sample size calculation

The sample size was calculated using the method to calculate the sample sizes for two independent samples

$H0: \mu 1 = \mu 2$ and $H1: \mu 1 \neq \mu 2$
and then

$$n = 2\left(\frac{Z_{1-\alpha/2} + Z_{1\text{-}\beta}}{ES}\right)^2$$

Where n=sample size, Z is the level of significance and ES is the effect size which can be calculated by

$$ES = \frac{|\mu_1 - \mu_2|}{\sigma}$$

Where μ is mean of population and σ is the standard of deviation of outcome of interest.

We assume μ 1=1.2 N in a non TCO group and μ 2=1.1 N in a TCO group with standard deviation σ=0.1. The level of significance is assigned 5% and power of the test is considered at 80%.

3.3 Materials used to fabricate TCO

The materials used in this study, Multiform® (Polyethylene closed cell foam) insole was 5 mm thick 30° Shore A hardness, Plastazote® (Polyethylene closed cell foam) 8 mm 25° Shore A harness and Microcellular rubber 10 mm 70° Shore A. A three layers material (Multiform®, Plastazote®and Microcellular rubber) was used to fabricate a TCO

(Figure 1). A certified prosthetist and orthotist took foam impression of the patient's feet followed by the weight bearing imprints. The foam was compressed enough to capture the foot structure with knee 90° and neutral sub-talar joint. The plaster mold was modified according to the imprints of the feet. The metatarsal pads were built within the positive mold 5 mm proximal to the metatarsal heads and 3-5 mm at its deepest point (3 mm for skinny feet and vice versa).

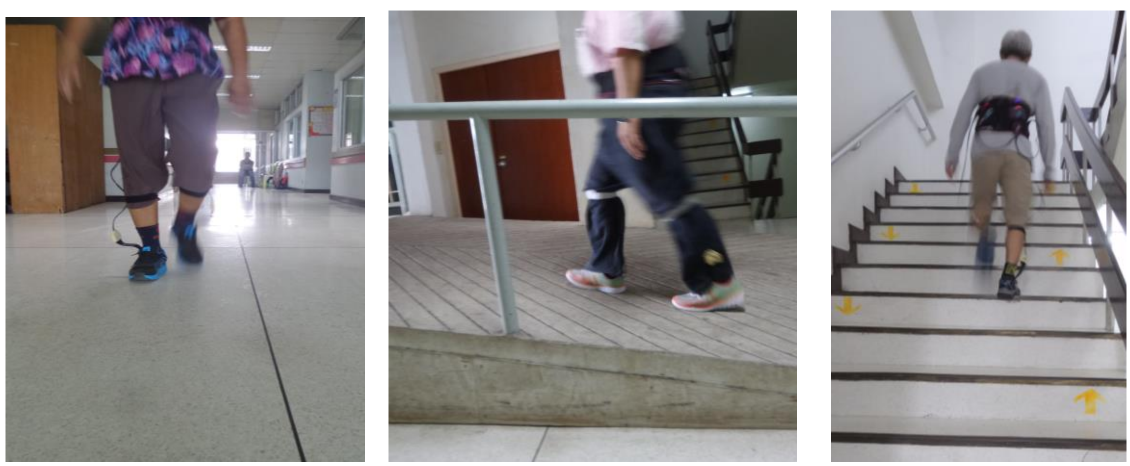
Figure 1 Total contact orthosis comprised of Multiform (top layer full length), Plastazote® (2nd layer full length) and microcellular rubber (3rd layer from hindfoot to midfoot)

3.4 Plantar pressure assessment

Participants were asked to perform 3 walking activities; level walking (10m), incline walking (8.04°) for 4m and 10 steps (step height 17.5 cm and 29 cm deep) stair walking without and with TCO (Figure 3). Each activity is performed for 3 rounds without any supportive devices and handrails. After each activity the subjects were asked to rest for 5-10 minutes and ensure they can perform next activities. The plantar pressure data was collected using Pedar-X® system (Novel GmbH, Munich, Germany) which was composed of 2.6 mm thick insoles (size W = Asian shoe size 26-26.5 and size X = Asian shoe size 27-27.5) and the Pedar® box (A/D converter). Zero calibration for each insole followed the manufacturer's instructions before the measurement (Figure 2c). Before starting the experiment, subject stand on left leg first followed by the right leg for 6-9 seconds. The subjects were asked to walk for a round or two after calibration to get familiar with the TCO and Pedar® insoles before recording data. The foot was divided in to four regions; toes, forefoot, midfoot and hind foot using masking software. The Pedar-X® system has an inbuilt threshold of 15 kPa that results in a cut-off value in pressure recording to reduce the noise while recording the in-shoe data. Appropriately sized Pedar insoles were placed in each subject shoes and the data were sampled at 100 Hz (Figure 2a-b).

(a) (b) (c)

Figure 2 Pedar® insole (a), placement of Pedar® insole with the TCO in subject shoes (b), calibration of Pedar® insole with the subject standing on one leg (c).



(a) (b) (c)

Figure 3 Different walking activities level walking (a), ramp walking (b) and stair walking (c).

3.5 Statistical analysis

Measured data were analyzed with the Novel Database Essential software version 12.3. The descriptive statistics of data were presented as mean and standard deviation. The statistical analysis was done using Prism 5.0 windows version (GraphPad software, San Diego, USA). The paired t-test was used to assess the plantar pressure and derived parameters in each subject with and without the TCO. The statistical significance for the test was set at $P < 0.05$.

4. Result and Discussion

4.1 Subject Characteristics

Sixteen subjects with diabetic neuropathy complete the study protocol. The characteristics of the subjects are shown in Table 1. The diabetic patients were identified in range of overweight as the body mass index was higher. The subjects had duration of diabetes (8.37 ± 4.50 years) and were found with calluses at big toe, metatarsal head or hallux valgus deformity. All subjects completed three activities with and without total contact orthosis.

4.2 Placement of sensor insoles under TCO and in-between foot and TCO

Information concerning plantar pressure is important for diagnosis of various foot pathologies and their orthotic intervention. The plantar pressure can be obtained using in-shoe systems which are commercially available as plantar surface of diabetic feet provide the primary surface of interaction during gait. The placement of in-shoe insole is still unclear, when placing the in-shoe insole under total contact orthosis (TCO) and above TCO in diabetic subjects. The peak plantar pressure values at toes and hindfoot during level walking were statistically different between under TCO and above TCO (Figure 4). The peak plantar pressure at mid-foot and hind-foot under TCO was higher than that measured above TCO. There was no significant difference for forefoot, midfoot and hindfoot during ramp ascending; ramp descending, stair ascending and stair descending except for toes (Figure 5-8). The peak plantar pressure at toes and forefoot measured under the TCO was less than the peak plantar pressure measured above the TCO whereas the contact area was greater while placing the Pedar® insole under the TCO compared to the placement above the TCO. Even there were differences in plantar pressure measurement between the placements of Pedar® insole; the trend of measurement was not statisticlly different. Therefore the sensor insoles were then placed under the TCO to complete the study.

Table 1 Demographic data of subjects

Parameters	Mean	SD
No. of subjects	16 (9 Males, 7 Females)	
Age (year)	58	9
Height (cm)	158.25	7.53
Weight (kg)	73.27	14.11
Body mass index (kg/m^2)	28.74	4.75
Duration of diabetes (years)	8.37	4.50
Callus at big toe (% of patients)	62.50	-
Callus at metatarsal heads (% of patients)	81.25	-
Hallux valgus (% of patients)	31.25	-

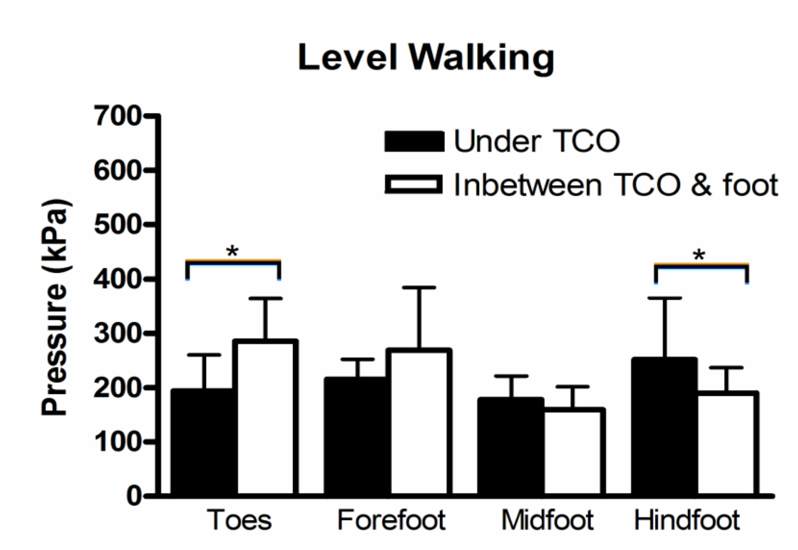


Figure 4 Peak plantar pressure during level walking in two conditions (Under TCO and in-between TCO and foot) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$).

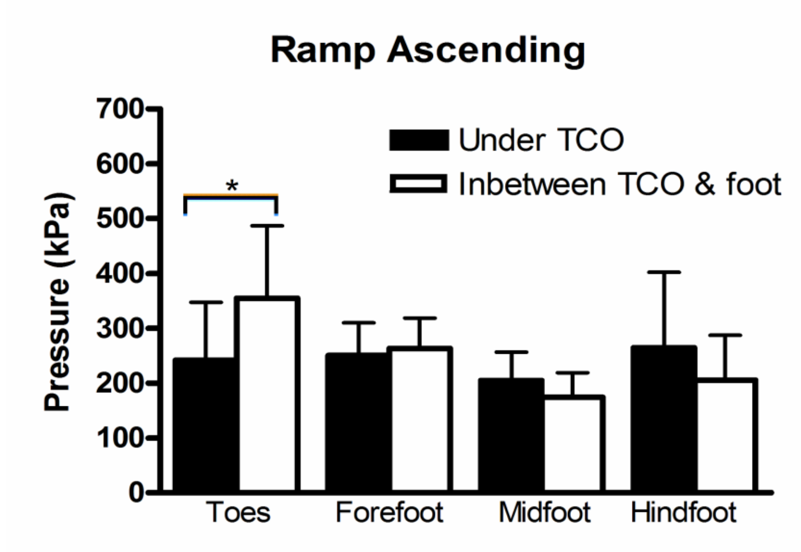


Figure 5 Peak plantar pressure during ramp ascending in two conditions (Under TCO and in-between TCO and foot) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$).

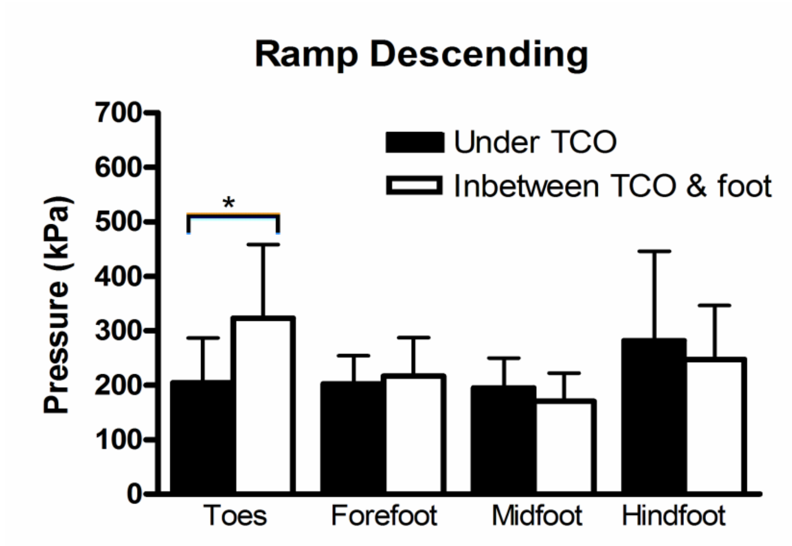


Figure 6 Peak plantar pressure during ramp descending in two conditions (Under TCO and in-between TCO and foot) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$).

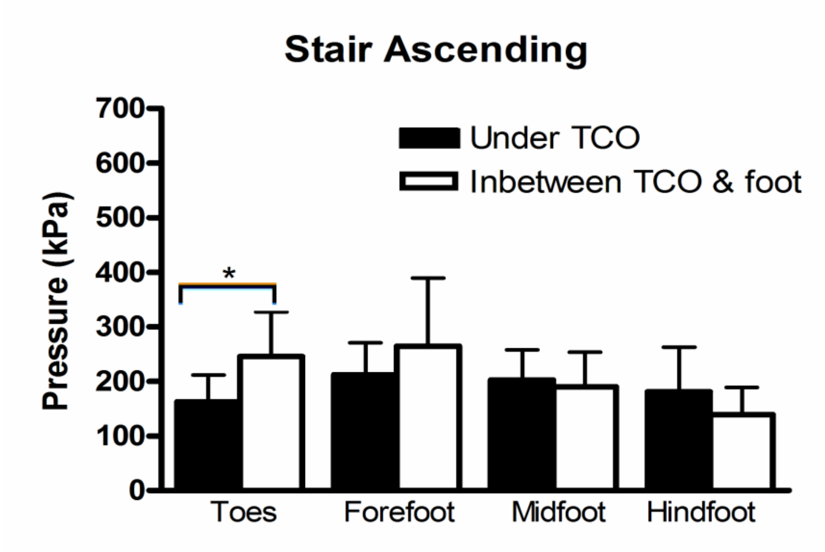


Figure 7 Peak plantar pressure during stair ascending in two conditions (Under TCO and in-between TCO and foot) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$).

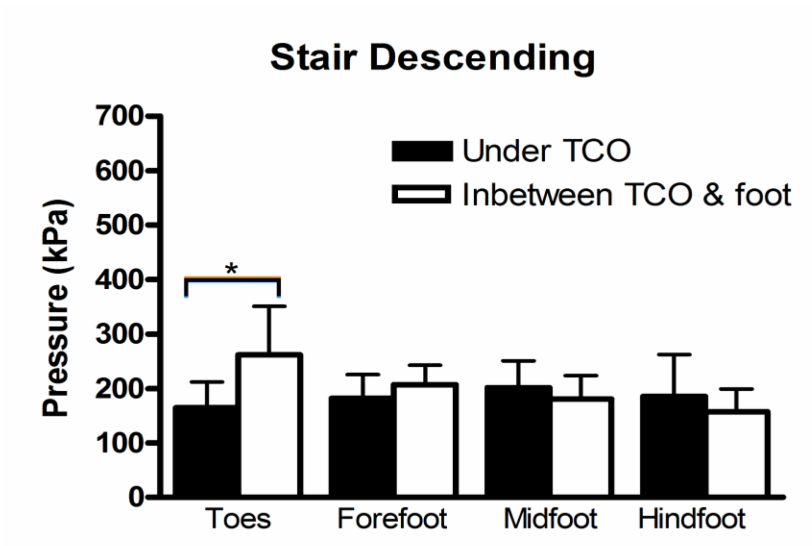


Figure 8 Peak plantar pressure during stair descending in two conditions (Under TCO and in-between TCO and foot) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$).

4.3 Plantar pressure and walking activities

During level walking the peak plantar pressure in the forefoot and toe regions were significantly reduced with the TCO ($P \leq 0.001$) (Figure 9). The peak plantar pressure at toes and forefoot during ramp ascending and ramp descending were significantly difference ($P \leq 0.01$ and $P \leq 0.001$, respectively) (Figure 10-11). However, similar results were found with the TCO for stair ascending and stair descending ($P \leq 0.01$ and $P \leq 0.001$, respectively) (Figure 12-13).

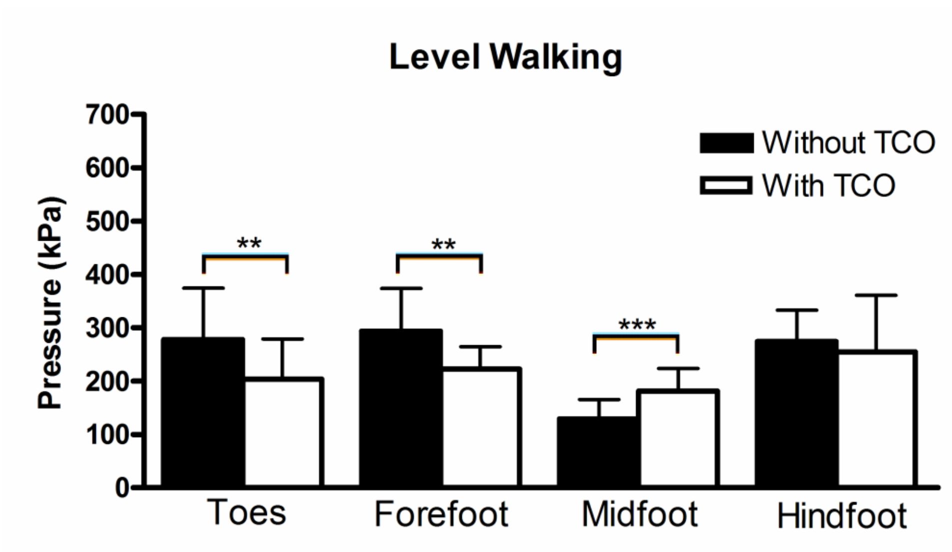


Figure 9 Peak plantar pressure during level walking in two conditions (without the TCO and with the TCO) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with ** (P < 0.01) and ***(P<0.001).

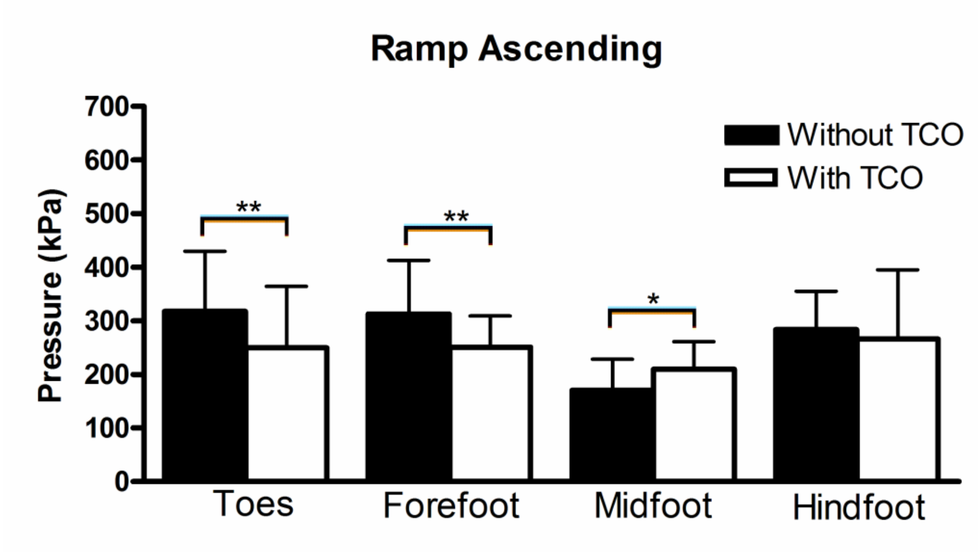


Figure 10 Peak plantar pressure during ramp ascending in two conditions (without the TCO and with the TCO) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$) and ** ($P < 0.01$).

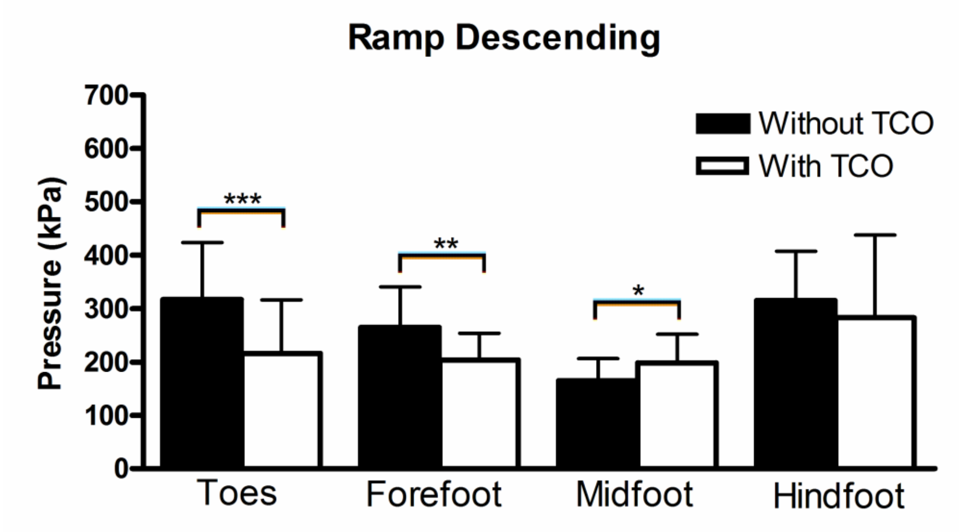


Figure 11 Peak plantar pressure during ramp descending in two conditions (without the TCO and with the TCO) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * ($P < 0.05$), ** ($P < 0.01$) and ***($P<0.001$).

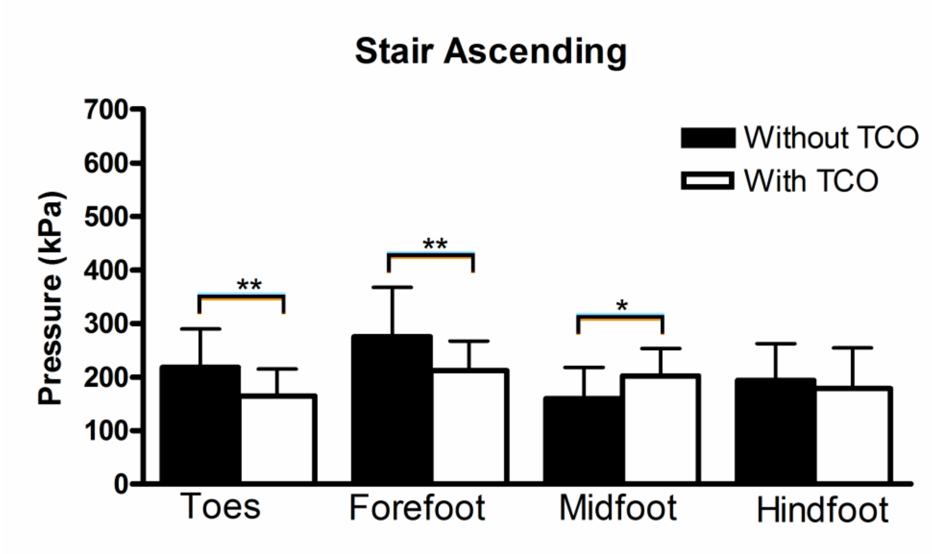


Figure 12 Peak plantar pressure during stair ascending in two conditions (without the TCO and with the TCO) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with * (P < 0.05) and ** (P < 0.01).

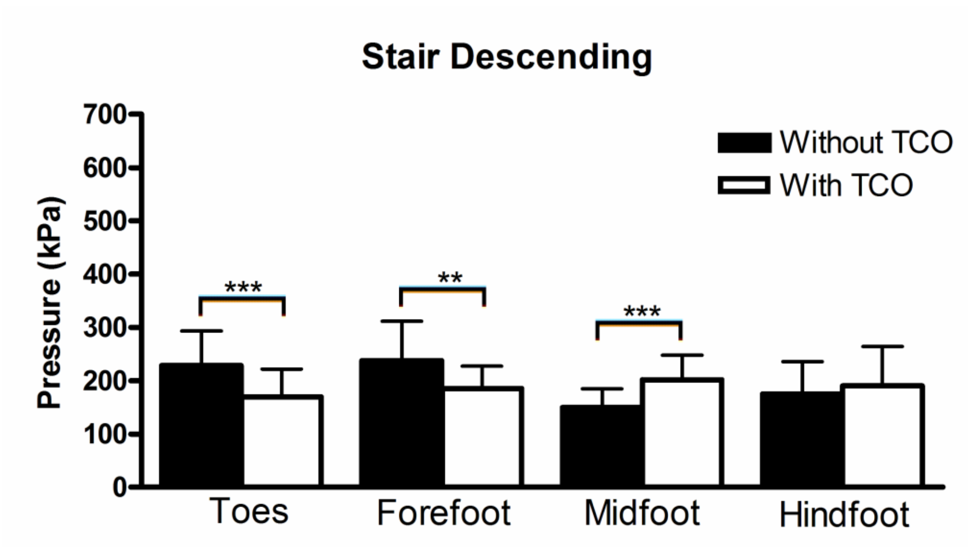


Figure 13 Peak plantar pressure during stair descending in two conditions (without the TCO and with the TCO) of four foot regions: toes, forefoot, midfoot and hindfoot. Significant differences between conditions are displayed with ** (P < 0.01) and ***(P<0.001).

The toes showed higher peak plantar pressure during ramp ascending and ramp descending compare to other walking activities (Figure 14). In the forefoot region, the peak plantar pressure during ramp ascending was the highest, whereas in stair descending the peak plantar pressure was the lowest (Figure 15). In the midfoot region, the peak plantar pressure during level walking was the lowest compared with other walking activities (Figure 16). However hindfoot region, ramp descending had the highest peak plantar pressure among the walking activities, while it was the lowest during stair walking (Figure 17). Additionally, it was observed that stair walking had the lowest peak plantar pressure among the walking activities in the toes and hindfoot regions. Both without and with TCO showed a quite similar trend of peak plantar pressure in four regions of the foot.

The force-time integral without the TCO and with the TCO during different activities, no significant differences were found between two conditions as shown in Figure 18 A. However the highest force time integral was found during stair walking compared to other walking activities. The contact area was highest for level walking compare to stair walking as shown Figure18 B. The significant difference between two conditions was observed during level walking ($P < 0.001$), whereas the contact area increased when wearing the TCO in other walking activities but it was not statistically significantly different. Pressure mapping indicated that the pressure redistribution of peak plantar pressure in each activity while using the TCO (Figure 19) and with an increase in the contact area.

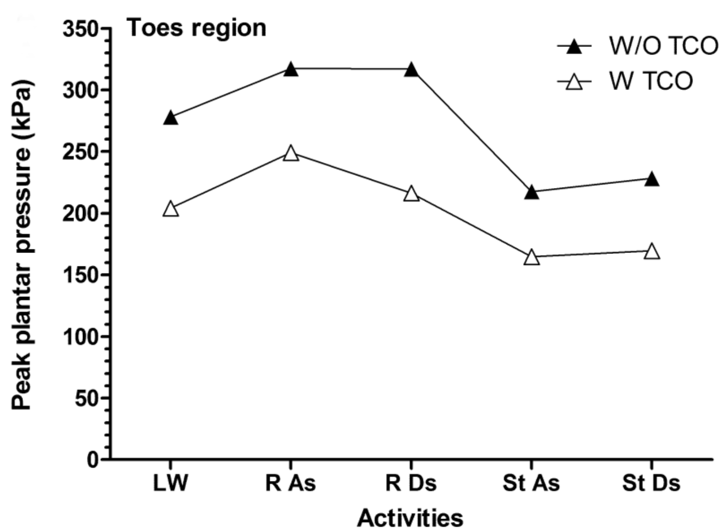


Figure 14 Plantar pressure during level walking (LW); ramp ascending (R As); ramp descending (R Ds); stair ascending (S As); stair descending (S Ds) for toes in two conditions: without the TCO (W/O TCO) and with the TCO (W TCO).

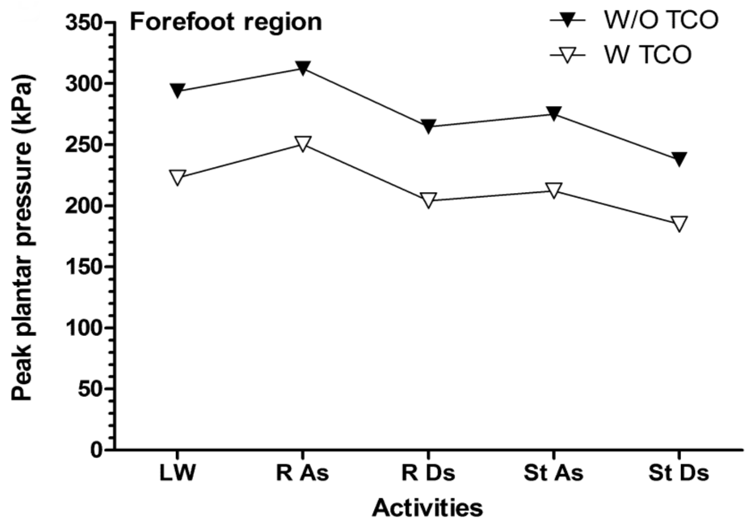


Figure 15 Plantar pressure during level walking (LW); ramp ascending (R As); ramp descending (R Ds); stair ascending (S As); stair descending (S Ds) for forefoot in two conditions: without the TCO (W/O TCO) and with the TCO (W TCO).

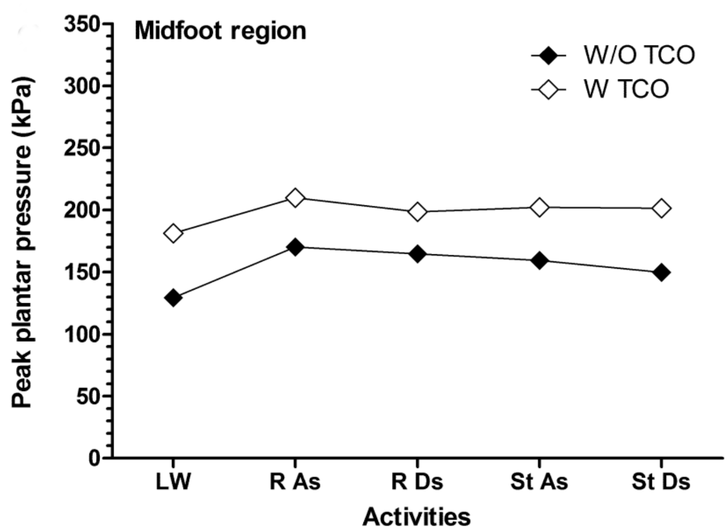


Figure 16 Plantar pressure during level walking (LW); ramp ascending (R As); ramp descending (R Ds); stair ascending (S As); stair descending (S Ds) for midfoot in two conditions: without the TCO (W/O TCO) and with the TCO (W TCO).

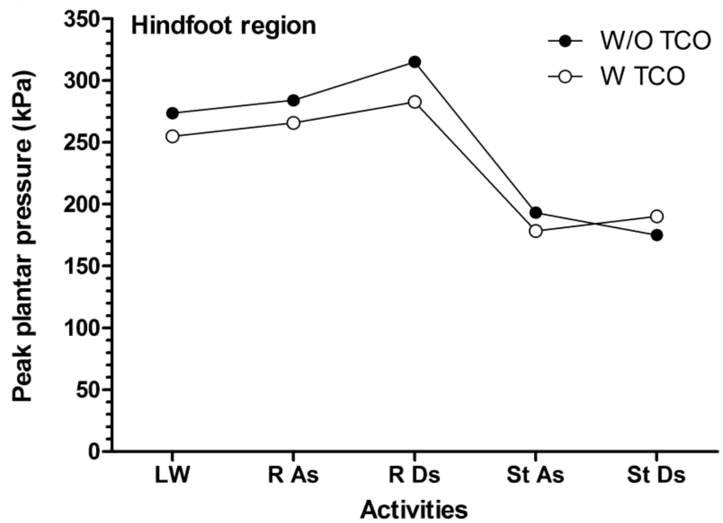


Figure 17 Plantar pressure during level walking (LW); ramp ascending (R As); ramp descending (R Ds); stair ascending (S As); stair descending (S Ds) for hindfoot in two conditions: without the TCO (W/O TCO) and with the TCO (W TCO).

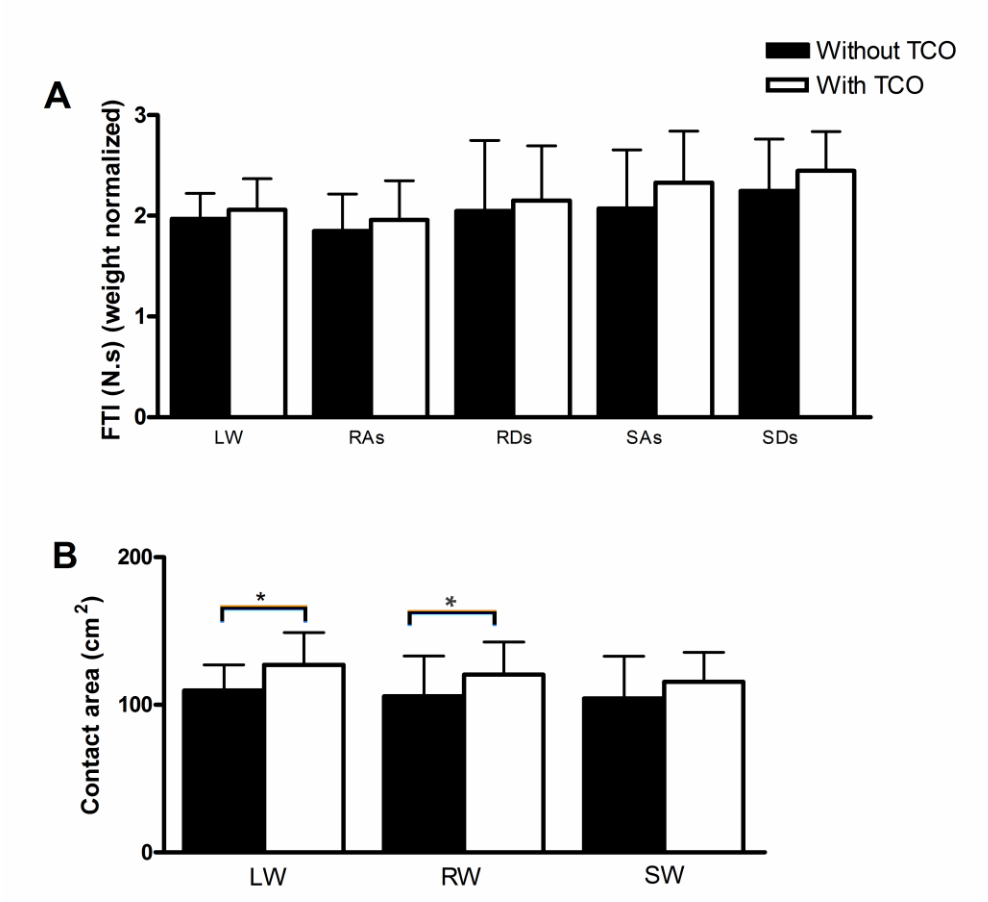


Figure 18 Force time integral (FTI) and contact area during level walking (LW); ramp walking (RW); ramp ascending (RA); ramp descending (RD); stair walking (SW); stair ascending (SA); stair descending (SD) in two conditions: without the TCO and with the TCO. Significant differences between conditions are displayed with * ($P < 0.05$).

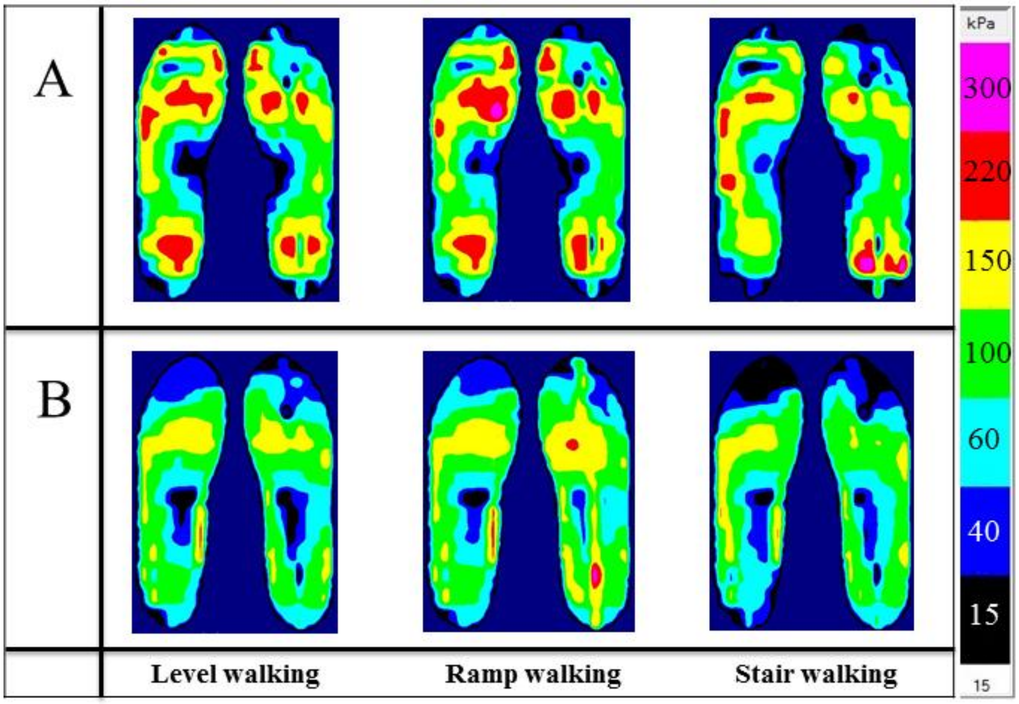


Figure 19 Pressure mapping during level walking, ramp walking and stair walking without the TCO (A) and with the TCO (B).

The most important findings of our study proved that TCO tend to reduce the plantar pressure by redistribution of pressure. The redistribution of plantar pressure, using TCO has an effect on the forefoot region with an agreement with the previous results (29, 30). To reduce number of patients with ulceration this study compares peak plantar pressure between two conditions during different walking activities in neuropathic diabetic subjects. The highest peak plantar pressures during walking activities were collected. Toes and forefoot showed the highest peak plantar pressure during level walking and ramp walking without the TCO, where reduction occur by 31.77% during ramp descending and by 24.15% during level walking with the TCO. The midfoot showed increased peak plantar pressure with the TCO. However, the TCO reduced the peak plantar pressure from the heel during ramp descending by 10.2%.

The foot acts as a flexible body during initial contact for shock absorption and then acts as a rigid body in order to propel the body forward during normal gait. However, the pathological feet with hallux valgus tend to disturb the forward propulsion of the body during the terminal phase of the gait cycle which results in a high peak plantar pressure at the big toe and metatarsal heads. The contact area during the push-off phase is less which required more force in order to propel the body forward. (24, 31)

Diabetic patients with neuropathy experience a higher plantar pressure compared to patients without a neuropathy and normal subjects. (32, 33) Our findings showed that the peak plantar pressure was the highest for the toes and forefoot without the TCO during level walking and ramp walking which is in concordance with previous investigations. (6, 24) Without the TCO, our study showed level walking had a higher peak plantar pressure than stair ascending and stair descending in the toes, forefoot and hindfoot regions, but Rao and Carter reported that level walking in normal adult women had higher peak pressures in all regions including the midfoot. (28) Ramp ascending increased forefoot peak plantar pressure and was reduced at the hindfoot in normal subjects, whereas the opposite effect was observed during ramp descending. (34) Our results showed a similar trend while walking without the TCO with diabetes. Peak plantar pressure at the hindfoot during level walking, stair ascending and stair descending was reduced compared to ramp descending where the peak plantar pressure was the highest in normal subjects. (25, 35, 36) We obtained similar results for peak plantar pressure in diabetic subjects.

The custom-made orthoses were found to redistribute the plantar pressure by maximizing the total contact area and were found to be more effective than shoes only. Other studies reported that the peak plantar pressure could be reduced by 30-40% using a TCO with an increased contact area of the whole foot. (18, 37, 38) The arch support and metatarsal pads in combination shift the pressure from the hindfoot and forefoot to the midfoot and prevent the foot from pronation. (39-41) In our study, we also found similar results with a reduction of the peak plantar pressure while using a TCO during all activities.

5. Concluding remarks and future work

In this study, we measured plantar pressure without TCO and with TCO of diabetic neuropathic foot. The pattern of plantar pressure is different for four regions of the foot during different walking activities. The highest pressure for the toes, forefoot without TCO was during ramp ascending, ramp descending and level walking, however lower pressure was found during stair ascending and stair descending. The peak plantar pressure was reduced and redistributed with the TCO from the toes, forefoot and hindfoot. The midfoot showed higher plantar pressure with the TCO during all activities, as the load transferred from the forefoot to midfoot. In addition to plantar pressure the contact area also increased with the use of TCO.

This work quantified the clinical prescription of the TCO for diabetic patients with diabetic feet. For patients with diabetic feet who are at high risk for developing ulcers, TCO in a combination with stable shoes resulted in lower plantar pressure. TCO is effective for diabetic feet where it offloads and redistributes the peak plantar pressure from the low tolerance area to high tolerance area during walking activities.

Further studies are necessary to investigate the lateral and medial regions of the foot with an increased number of subjects in order to design the effective TCO for patients who have diabetic feet. Furthermore, severe cases with foot complications need to be addressed as this work only emphasizes on initial stages of diabetic foot.

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Appendix A

Submitted Manuscript

Muhammad Nouman, Wipawan Leelasamran, and Surapong Chatpun. Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities **(Submitted to Foot & Ankle International)**

Foot & Ankle International

Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities

Journal:	*Foot & Ankle International*
Manuscript ID	FAI-16-0555.R2
Manuscript Type:	Basic Science Research Article
Keywords:	Total contact orthosis, Biomechanics, Plantar pressure, Ulceration, Walking activities, Diabetic foot

STRUCTURED ABSTRACT (Limit 250 words) Background, Methods, Results & Conclusion:	Background: Using a total contact orthosis (TCO) is an effective method to off-load in diabetic patients with foot neuropathy. However, the redistribution of peak plantar pressure is mostly observed during level walking which may differ from other walking activities. The aim of this study was to investigate the plantar pressure from four regions of the foot during different walking activities (level walking, ramp ascending, ramp descending, stair ascending and stair descending) in neuropathic diabetic subjects with and without a TCO. Methods: Sixteen neuropathic diabetic subjects aged 40-60 years with calluses and hallux valgus were included in this study and were provided with TCOs made up of multifoam, Plastazote® and microcellular rubber. The plantar pressure and contact area with the TCO and without the TCO were recorded using the Pedar X® system during different walking activities. Results: A significant reduction of plantar pressure during different walking activities at the toes and forefoot regions were observed while walking with the TCO compared to walking without the TCO (control condition). Plantar pressure increased at the midfoot region when walking with the TCO and no significant difference was observed at the hindfoot region between the control and TCO conditions. Furthermore, maximum contact area was observed during level walking with the TCO compared to other walking activities. Conclusion: The TCO significantly reduced and redistributed the peak plantar pressure from the sites where the ulceration rate is higher at the toes and forefoot compared to the other regions of the foot.

Paper No. FAI-16-0555.R1 entitled "Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities"

Reviewer #1:

COMMENT	RESPONSE	TEXT CHANGES
General Comments: I recommend that the authors have their manuscript proofed by a writing center for grammatical and syntax inconsistencies. For example, Lines 37 – 39 present grammatical errors which should be remedied prior to acceptance for publication. These grammatical issues make the manuscript more difficult to read which may limit its impact on future research.	Thank you for this recommendation. We have edited the grammatical and syntax inconsistencies (Lines 37-39). We also asked Mr. Glenn Shingledecker, our staff at the International Affairs Office, Faculty of Medicine, to proofread this revision.	Even though an ulcer had healed completely through medical therapy, the chance of re-ulceration was still high (30-40%) within the first year after healing.[6,28,35]
Introduction		
Last two paragraphs before the Materials and Methods (Lines 64-72) could be combined.	Thank you for this suggestion. We have combined them.	
Methods		
The sample size is small. This cannot be altered. However, due to the small sample size, I suggest the use of Cohen's d to present effect sizes (Cohen 1988). This will confirm that the statistical differences are of significant effect while it may provide greater insight into the non-significant findings. Please include these as well as p-values.	Thank you for this suggestion. We have calculated Cohen's *d* effect size and presented the values in Table 2 as well as we put the *p* value of the t-test in this table. We have already addressed this calculation in the Materials and Methods section (Lines 122-123).	Furthermore, we calculated a Cohen's *d* effect size to confirm the magnitude of differences between the conditions.[9]
Results		
I suggest including Cohen's d for effect sizes. This will confirm the magnitude of differences between the groups/conditions.	We presented Cohen's *d* for effect sizes in Table 2 (Lines 140-144).	Table 2 shows Cohen's *d* effect sizes of a comparison between two conditions in each activity. The effect sizes were in medium to very large for 3 regions of the foot (toes, forefoot, and midfoot). The t-test showed a significant difference in each walking activity.
Artwork		
Figure 5 – please note that this is from a single, representative	We have additionally addressed in the figure	Fig. 5. Pressure mapping during level walking,

COMMENT	RESPONSE	TEXT CHANGES
subject.	legend that it is from a single representative subject.	ramp walking and stair walking in a control condition (A) and with TCO (B) from a single representative subject.

Reviewer #2:

COMMENT	RESPONSE	TEXT CHANGES
Introduction		
would recommend proof-reading for grammar and syntax work so that the introduction reads more clearly	Thank you for this recommendation. We have edited the grammatical and syntax inconsistencies. We also asked Mr. Glenn Shingledecker, our staff at the International Affairs Office, Faculty of Medicine, to proofread this revision.	
Methods		
line 81 - it is not clear if you mean that they were included if they do or do not have a history of foot callus?	We apologize for these unclear words. We have revised them (Line 80).	The inclusion criteria were age 40 to 60 years, type II diabetes, history of having callus at forefoot or hindfoot at the time of evaluation, having forefoot deformity (ie, hammer toes, mallet toes or hallux valgus),…
Discussion		
lines 207/208 - the sentence that begins "Furthermore..." is over-reaching. Suggest changing the word "overcome" and explaining that education and orthoses are two important factors in the prevention of diabetic ulcer. As it is worded, it sounds like you are saying that TCO and education are superheroes.	Thank you for this comment. We have revised it by deleting this sentence and only say "The present study also contributes towards the proper management of diabetic foot ulceration." (Lines 211-212).	The present study also contributes towards the proper management of diabetic foot ulceration.
Conclusion		
Better but needs reorganization to read more clearly. The second sentence is a topic sentence and	We have re-arranged the sentences according to the reviewer's suggestion	Using a total contact orthosis can effectively reduce and redistribute

COMMENT	RESPONSE	TEXT CHANGES
should probably be first in the paragraph.	(Lines 225-229).	plantar pressures from the toes and forefoot to the metatarsal shafts and midfoot during walking activities. Ramp walking resulted in higher peak pressures than in other walking activities in both the control condition and with the total contact orthoses.

Editor(s)' Comments to Author:

Please see comment of reviewer above and note that they did recommend that the paper be edited by an English translating service.

We have asked Mr. Glenn Shingledecker, our staff at the International Affairs Office, Faculty of Medicine, to proofread this revision before re-submission.

Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities

Abstract:

Background: Using a total contact orthosis (TCO) is an effective method to off-load in diabetic patients with foot neuropathy. However, the redistribution of peak plantar pressure is mostly observed during level walking which may differ from other walking activities. The aim of this study was to investigate the plantar pressure from four regions of the foot during different walking activities (level walking, ramp ascending, ramp descending, stair ascending and stair descending) in neuropathic diabetic subjects with and without a TCO.

Methods: Sixteen neuropathic diabetic subjects aged 40-60 years with calluses and hallux valgus were included in this study and were provided with TCOs made up of multifoam, Plastazote® and microcellular rubber. The plantar pressure and contact area with the TCO and without the TCO were recorded using the Pedar X® system during different walking activities.

Results: A significant reduction of plantar pressure during different walking activities at the toes and forefoot regions were observed while walking with the TCO compared to walking without the TCO (control condition). Plantar pressure increased at the midfoot region when walking with the TCO and no significant difference was observed at the hindfoot region between the control and TCO conditions. Furthermore, maximum contact area was observed during level walking with the TCO compared to other walking activities.

Conclusion: The TCO significantly reduced and redistributed the peak plantar pressure from the sites where the ulceration rate is higher at the toes and forefoot compared to the other regions of the foot.

Level of evidence: Therapeutic-level II, lesser quality randomized controlled trial (RCT)

Keywords: Diabetic foot; Total contact orthosis; Biomechanics; Plantar pressure; Ulceration; Walking activities

Introduction

Excessive peak plantar pressure is the most common cause of ulceration in the presence of foot deformity or neuropathy. Foot deformities result in an abnormal gait pattern and neuropathy additionally causes an abnormal plantar pressure.[1,4,21,31,34] Prolonged abnormal plantar pressure at a specific site increases the chance of ulceration.[11] It has been reported that 67% of all lower extremity amputations were preceded by diabetic foot ulceration.[36] Even though an ulcer had healed completely through medical therapy, the chance of re-ulceration was still high (30-40%) within the first year after healing.[6,28,35] Diabetic foot ulcerations and amputations are serious complications linked to diabetes and have an effect on the individual and also on society.[32] The life-time incidence of foot ulceration is 25% of those with diabetes.[8,37] Callus formation is usually caused by shear forces between the footwear and the foot under the bony prominences where the pressure leads to break down of the skin.[16] Repetitive peak dynamic plantar pressures considerably increase the possibility of foot ulcers in patients with peripheral neuropathy.[31]

Plantar pressure usually changes while changing activities in healthy subjects without foot abnormalities.[21] Stair walking is a common activity that requires a higher demand than level walking. During stair descending, the reduction of peak plantar pressure occurs from hindfoot compared to level walking. However, incline walking increases the forefoot plantar pressure but reduces the hindfoot plantar pressure.[12,30] Level walking may not reflect plantar pressure during other walking activities especially in patients with gait impairments.[5,22] Plantar pressure measurements give important information for the design of an insole that can reduce the peak plantar pressure.[33] In a clinical setup, diabetic patients are provided with a customized total contact orthosis (TCO).[3,23] The effectiveness of a TCO is based on the reduction of the peak plantar pressure during different walking activities from the sites where a high rate of ulceration and re-ulceration occurs.[7,16,30]

It was reported that high plantar pressure can be minimized through the use of a TCO in a combination with stable shoes.[10] Several studies compared the load distribution of a custom-made insole with a prefabricated insole. The custom-made insole was considerably better when compared with the prefabricated insole in terms of plantar pressure distribution and contact area.[25] We found very few studies that investigated the effectiveness of total contact orthosis in diabetic patients. There is still limited information regarding different walking activities and the effectiveness of a TCO in the diabetic population.

With an understanding of a specific activity that results in higher plantar pressure and the regions of the foot where high plantar pressure occurs, the load distribution can be managed effectively through a TCO. A positive approach towards management of diabetic foot ulceration through a TCO by understanding the activities can reduce the number of foot complications and lower limb amputations. The aim of this study was to investigate the plantar pressure at four regions of the foot during different walking activities (level walking, ramp ascending, ramp descending, stair ascending and stair descending) in diabetic neuropathic subjects with and without a TCO.

Materials and methods

Subject recruitment

The sample size of 16 neuropathic diabetic subjects was determined by the inference for mean method. The subjects were informed of the details of the research after approval from the research ethics committee of the Faculty of Medicine. All of the participants read and signed the informed consent. The inclusion criteria were age 40 to 60 years, type II diabetes, history of having callus at forefoot or hindfoot at the time of evaluation, having forefoot deformity (i.e. hammer toes, mallet toes or hallux valgus), blood pressure not exceeding

140/90 mmHg, having insensate or diminished sensation noted with a 10 g monofilament and able to walk independently at least 10 m at a self-selected speed. The subjects were excluded if they had foot ulcerations, joint surgery of lower limb or the presence of an unhealed open wound at the time of the experiment, a partial or total amputation, ischemic heart disease or unable to understand the simple instructions given during the study protocol.

Total contact orthosis fabrication

A certified prosthetist and orthotist took foam impressions of the feet of the subjects in order to make positive plaster molds. The foam was compressed to capture the foot and medial longitudinal arch with the knee at 90 degrees and a neutral sub-talar joint. The positive mold was modified according to the blueprint obtained from the standing subject bearing equal weight on both feet. The TCO was fabricated using multifoam as the top layer, Plastazote® as the second layer and microcellular rubber as the final stabilizing layer. The TCO was then fitted inside the sport shoe with a 0.5 cm heel height. Similar shoes were given to each subject in order to minimize the experimental variation.

Plantar pressure assessment

Subjects were asked to perform three walking activities: level walking for 10 m, walking on an inclined surface (8.34°) for 4 m and 10 steps (step height 17.5 cm and 29 cm in depth) of stair walking. Two conditions were set up: the control condition without the TCO and with the TCO. Three rounds of each walking activity were performed without the use of a walking aid or handrail. Subjects had 10 minutes to rest after each walking activity. The plantar pressure was recorded using the Pedar-X® system (Novel GmbH, Munich, Germany) which was composed of 2.6 mm thick insoles (size W = Asian shoe size 26-26.5 and size X = Asian shoe size 27-27.5) and the Pedar® A/D converter. Each of the Pedar® insoles was calibrated to zero before starting the experiment by asking the subjects to stand on the left leg first and followed by standing on the right leg for 6-9 seconds for each leg. Then the subjects were asked to walk for a round to get familiar with the TCO and Pedar® insoles before recording the data. We defined the foot into 4 regions: toes, forefoot, midfoot and hindfoot (Figure 1). The Pedar-X® system has an inbuilt threshold of 15 kPa that results in a cut-off value in pressure recording to reduce the noise while recording the in-shoe data. Appropriately sized Pedar® insoles were placed in each shoe of the subjects and the data were sampled at 100 Hz.

Data and statistical analysis

The plantar pressure and contact area were obtained from the Novel Database Essential software version 12.3. Furthermore, the force-time integral (area under the curve) was analyzed using our in-house computer algorithm. The descriptive statistics of data were presented as mean and standard deviation. The statistical analysis was done using Prism 5.0 Windows version (GraphPad software, San Diego, CA, USA). The paired t-test was used to assess the plantar pressure and derived parameters between the control condition and with the TCO. The statistical significance for the test was set at $P < .05$. Furthermore, we calculated a Cohen's *d* effect size to confirm the magnitude of differences between the conditions.[9]

Results

The demographic data of the subjects are shown in Table 1. The body mass index indicated that our subjects were in a range of overweight. The subjects had a long mean duration of diabetes (8.37 ± 4.50 years) and some subjects had big toe callus, metatarsal head (forefoot) callus or hallux valgus deformity. All subjects performed completely the three walking tasks without pause.

Figure 2 presents the peak plantar pressure during different walking activities in the control condition and with the TCO. During level walking with the TCO, the peak plantar pressures in the forefoot and toe regions were significantly reduced about 26% and 24%, respectively, compared to the control condition ($P < .01$) (Figure 2A). During ramp ascending and ramp descending with the TCO, there were significant differences for the toes and forefoot regions ($P < .01$ and $P < .001$) (Figure 2B-C). The same results were found while wearing the TCO for stair ascending and stair descending ($P < .01$ and $P < .001$, respectively) (Figure 2D, E). Furthermore, in each walking activity, we found that wearing the TCO significantly increased peak plantar pressure at midfoot compared to a control condition ($P < .05$ and $P < .001$). Table 2 shows the Cohen's *d* effect sizes and the t-test *p* values of peak plantar pressure differences between two conditions in four regions of the foot in each activity. The effect sizes were in medium to very large for 3 regions of the foot (toes, forefoot, and midfoot). The t-test of these 3 regions showed a significant difference in each walking activity.

Plantar pressures in each region for three walking activities are shown in Figure 3. For the control condition in the toes region, it was revealed that both ascending and descending ramp walking had a peak plantar pressure higher than other walking activities (Figure 3A). In the forefoot region, the peak plantar pressure in the control condition was highest during ramp ascending, whereas the peak plantar pressure was lowest in stair descending (Figure 3B). In the midfoot region, the peak plantar pressure during level walking was the lowest compared with other walking activities in both conditions (Figure 3C). In the hindfoot region for both conditions, ramp descending had the highest peak plantar pressure among the walking activities, whereas it was the lowest during stair walking (Figure 3D). Furthermore, it was noticed that stair walking had the lowest peak plantar pressure among the walking activities in the toes, forefoot and hindfoot regions. Whether wearing the TCO or not, it showed a quite similar trend of peak plantar pressure in every region.

The force-time integrals in the control and with the TCO conditions during different activities are shown in Figure 4A. There were no significant differences while the subjects walked with the TCO and without the TCO. The highest force time integral was found during stair walking compared to other walking activities.

The contact area was highest for level walking which was less during stair walking (Figure 4B). A significant difference in the contact area between the control condition and with the TCO was observed during level walking and ramp walking ($P < .001$ and $P < .05$), whereas the contact area also increased when wearing the TCO in other walking activities but it was not statistically significantly different. Pressure mapping indicated there was a redistribution of peak plantar pressure and an increase in the contact area in each activity when using the TCO as the examples show in Figure 5.

Discussion

Diabetic patients with neuropathy experience a higher plantar pressure compared with patients without a neuropathy and compared with normal subjects.[2,24,33] In this study, we found that the toes and forefoot regions had the highest peak plantar pressures during level walking and ramp walking in the control condition. When using the TCO, the peak plantar pressure in the toes region was reduced by 32% during ramp descending and by 24% during level walking. The midfoot region showed an increased peak plantar pressure with the TCO in every walking activity. However, the TCO reduced the peak plantar pressure at the heel region during ramp descending by 10%. These findings provided quantitative assessment results for plantar pressure reduction using the TCO.

During normal gait, the foot acts as a flexible body during initial contact for shock absorption and then acts as a rigid body in order to propel the body forward. However, the pathological feet with hallux valgus tend to disturb the forward propulsion of the body during the terminal stance phase of the gait cycle which results in a high peak plantar pressure at the big toe and metatarsal heads. Therefore, using the TCO in that case can be beneficial because our study clearly showed that the TCO could significantly reduce plantar pressure in the toes and forefoot regions in level walking.

As shown in our study, it was expected that different walking activities resulted in a variation of peak plantar pressure in each foot region. During level walking and ramp walking, toes and forefoot regions had higher plantar pressure for both control and with TCO conditions which is in concordance with previous investigations.[14,21] Furthermore, our study showed that level walking in the control condition had a higher peak plantar pressure than stair ascending and stair descending in the toes, forefoot, and hindfoot regions, but Rao and Carter reported that level walking in normal adult women had higher peak pressures in all regions including the midfoot.[29] Ramp ascending increased forefoot peak plantar pressure and was reduced at the hindfoot in normal subjects, whereas the opposite effect was observed during ramp descending.[13] Our results showed a similar trend while walking without the TCO with diabetes. Peak plantar pressure at the hindfoot region during level walking, stair ascending, and stair descending was reduced compared to ramp descending where the peak plantar pressure was the highest in normal subjects.[17,20,27] We obtained similar results for peak plantar pressure in diabetic subjects.

The custom-made orthoses can redistribute the plantar pressure by maximizing the total contact area and they are more effective than shoes only. Other studies reported that the peak plantar pressure could be reduced by 30-40% using the TCO with an increased contact area of the whole foot.[3,18,19] The arch support and metatarsal pads in combination shift the pressure from hindfoot and forefoot to midfoot and prevent the foot from pronation.[7,15,26] In our study, we also found that peak plantar pressure increased in the midfoot region, whereas the peak plantar pressure in other regions was reduced when using the TCO during all walking activities.

Our results indicate that the TCO allowed a significant increase in the contact area and redistribution of the peak plantar pressure from the metatarsal heads to the metatarsal shaft that provided support at the medial arch of the foot during all activities performed from four regions of the foot. The present study also contributes towards the proper management of diabetic foot ulceration.

There are several limitations in our study. We focused only on the initial stage of diabetic foot with no ulceration which might not completely represent the diabetic foot conditions. Only four regions of the foot could be masked due to the available version of the software. Therefore, we could not determine plantar pressure on the lateral and medial sides of the midfoot region. The TCOs were fabricated from materials available in our prosthetics and orthotics unit. The walking activities in this study were representative of activities but they may not represent the situations that the subjects encounter in their daily lives. Furthermore, customized casting conditions could affect the TCO fabrication and the pattern of pressure redistribution.

Conclusion

Using a total contact orthosis can effectively reduce and redistribute plantar pressures from the toes and forefoot to the metatarsal shafts and midfoot during walking activities. Ramp walking resulted in higher peak pressures than in other walking activities in both the control condition and with the total contact orthosis. Further studies that focus on the later stages of diabetic neuropathy, other daily activities, and the off-loading effectiveness of a total contact orthosis are necessary for the design and fabrication of total contact orthoses.

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Tables:

Table 1. Demographic data of subjects

Parameters	Mean	SD	Range
No. of subjects	16 (9 Males, 7 Females)		
Age (year)	58	9	40-59
Height (cm)	158.25	7.53	147-170
Weight (kg)	73.27	14.11	53-112
Body mass index (kg/m^2)	28.74	4.75	22-39
Duration of diabetes (years)	8.37	4.50	2-15
Callus at big toe (% of subjects)	62.50	-	N/A
Callus at metatarsal heads (% of subjects)	81.25	-	N/A
Hallux valgus (% of subjects)	31.25	-	N/A

N/A: not available

Table 2. Cohen's *d* effect sizes and t-test *p* values of the peak plantar pressure differences between two conditions: with the TCO and without the TCO (control) during level walking (LW); ramp ascending (RA); ramp descending (RD); stair ascending (SA); stair descending (SD) for four foot regions.

Activity	Toes		Forefoot		Midfoot		Hindfoot	
	Cohen's *d*	t-test *p* value	Cohen's *d*	t-test *p* value	Cohen's *d*	t-test *p* value	Cohen's *d*	t-test *p* value
LW	0.857	0.001	1.112	0.0014	1.310	0.0007	0.219	0.379
RA	0.600	0.007	0.753	0.0043	0.721	0.0304	0.177	0.606
RD	0.975	0.0001	0.944	0.0021	0.708	0.0284	0.252	0.317
SA	0.854	0.0031	0.823	0.0012	0.783	0.0142	0.202	0.490
SD	0.997	0.0008	0.876	0.0012	1.261	0.0001	0.225	0.476

Figure legends:

Figure 1. Regions of foot

Figure 2. Peak plantar pressure during different walking activities in two conditions of with TCO and without TCO (control) of four foot regions: toes, forefoot, midfoot, and hindfoot. Significant differences between conditions are displayed with *(P < .05), **(P < .01) and ***(P < .001).

Figure 3. Plantar pressure during level walking (LW); ramp ascending (RA); ramp descending (RD); stair ascending (SA); stair descending (SD) for four foot regions: A) toes; B) forefoot; C) midfoot; and D) hindfoot in two conditions: with TCO and without TCO (control).

Figure 4. Force time integral during and contact area level walking (LW); ramp walking (RW); ramp ascending (RA); ramp descending (RD); stair walking (SW); stair ascending (SA); stair descending (SD) in two conditions: with TCO and without TCO (control). Significant differences between conditions are displayed with *(P < .05) and ***(P < .001).

Figure 5. Pressure mapping during level walking, ramp walking and stair walking in a control condition (A) and with TCO (B) from a single representative subject.

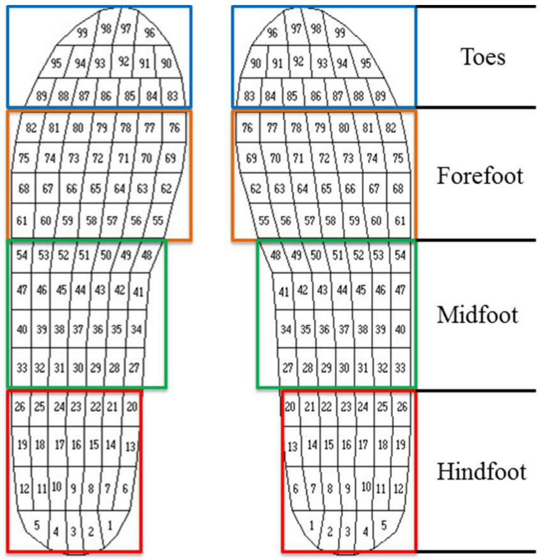

Figure 1. Regions of foot
Figure 1.
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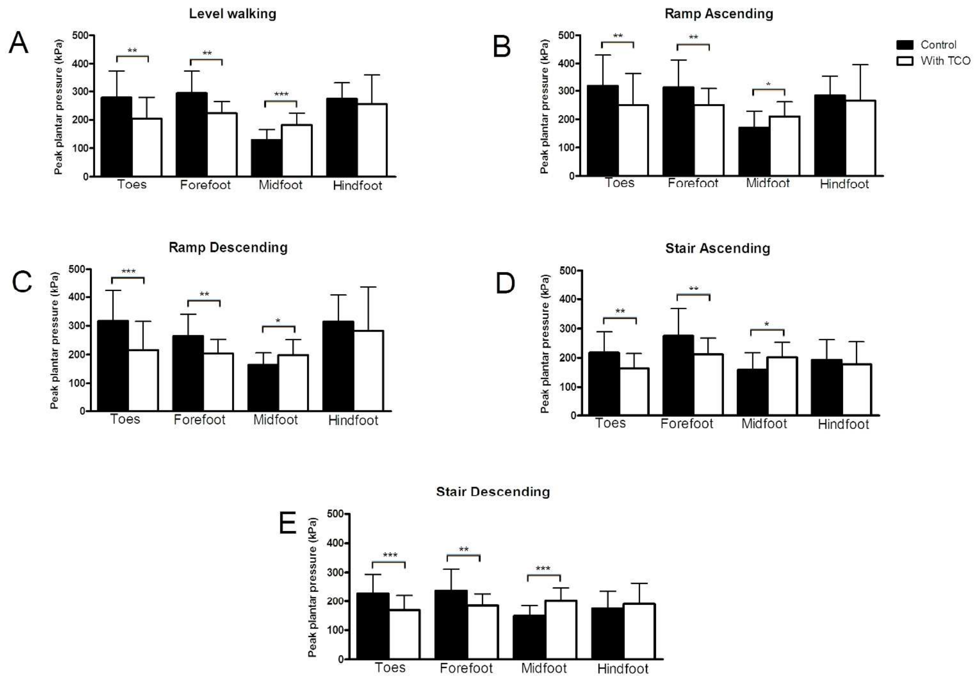

Figure 2. Peak plantar pressure during different walking activities in two conditions of with TCO and without TCO (control) of four foot regions: toes, forefoot, midfoot, and hindfoot. Significant differences between conditions are displayed with *(P < .05), **(P < .01) and ***(P < .001).

Figure 2

255x183mm (300 x 300 DPI)

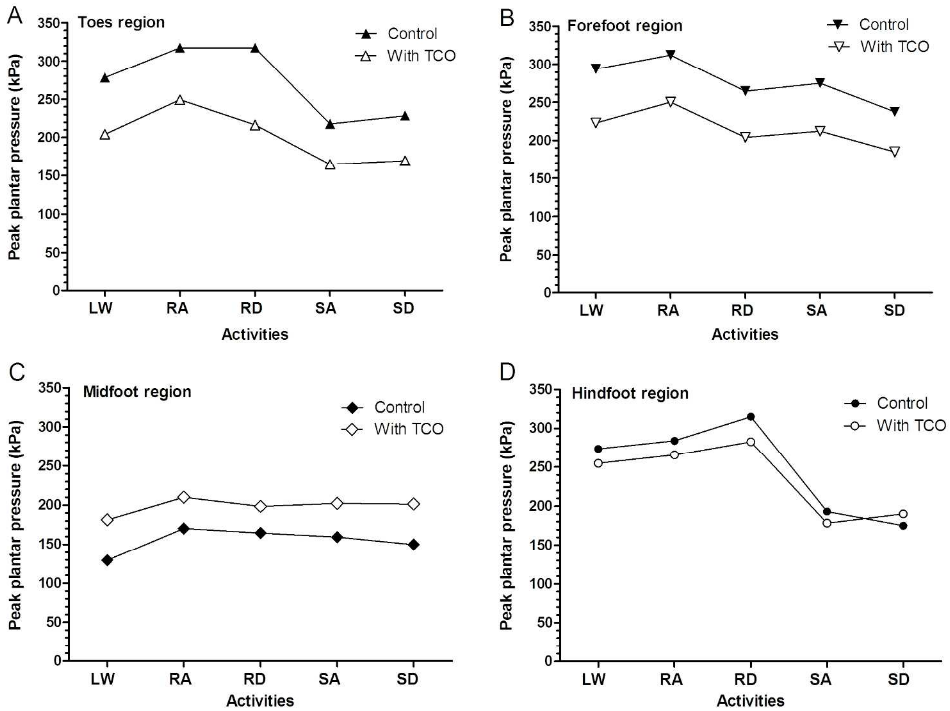

Figure 3. Plantar pressure during level walking (LW); ramp ascending (RA); ramp descending (RD); stair ascending (SA); stair descending (SD) for four foot regions: A) toes; B) forefoot; C) midfoot; and D) hindfoot in two conditions: with TCO and without TCO (control).
Figure 3
223x171mm (300 x 300 DPI)

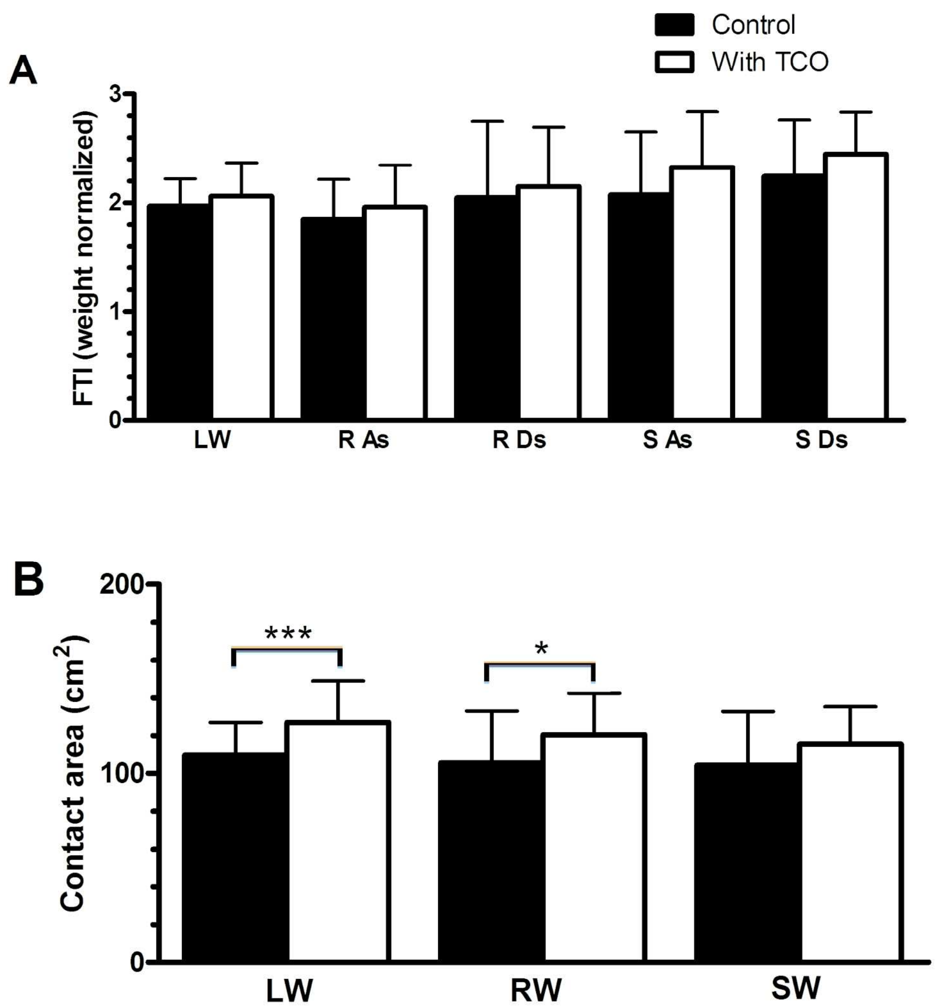

Figure 4. Force time integral during and contact area level walking (LW); ramp walking (RW); ramp ascending (RA); ramp descending (RD); stair walking (SW); stair ascending (SA); stair descending (SD) in two conditions: with TCO and without TCO (control). Significant differences between conditions are displayed with *(P < .05) and ***(P < .001).
Figure 4A
185x201mm (300 x 300 DPI)

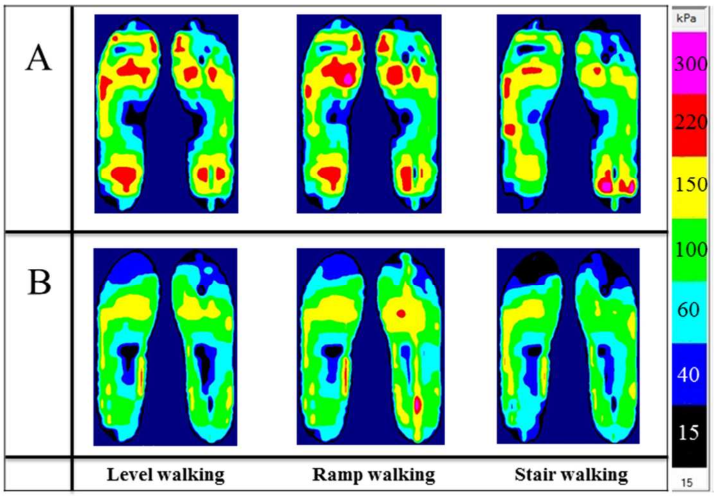

Figure 5. Pressure mapping during level walking, ramp walking and stair walking in a control condition (A) and with TCO (B) from a single representative subject.
Figure 5
254x190mm (96 x 96 DPI)

FAI-16-0555 – Reported Author Disclosures

Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities

Funding Information:

Graduate School of [redacted]

The Faculty of Medicine, [redacted]

[redacted]

Appendix B

Conference paper

Muhammad Nouman, and Surapong Chatpun. The role of total contact orthosis on plantar pressure distribution during stair walking in people with diabetes. The 30th Conference of The Mechanical Engineering Network of Thailand 5th-8th July 2016, Songkhla, Thailand. **(Conference proceeding)**


5th- 8th July 2016, PSU, Songkhla
Proceedings
The 30th Conference
of Mechanical Engineering Network of Thailand
การประชุมวิชาการเครือข่ายวิศวกรรมเครื่องกลแห่งประเทศไทย ครั้งที่ 30
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อ.เมือง จ.สงขลา

The Role of Total Contact Orthosis on Plantar Pressure Distribution during Stair Walking in People with Diabetes

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Abstract

Abnormal plantar pressures during ascending and descending stairs cause an adverse effect on the plantar load distribution in people with diabetic foot complications. However, limited data are available to examine the plantar peak pressure during stair ascending and descending in diabetic people. The aims of this study were: to assess the differences regarding in-shoe plantar pressure in patients with diabetes during stair ascending and descending and to assess the effects of TCO in plantar pressure distribution. Subjects without conditions affecting their ability to perform stair ascending and descending activity were recruited. Each participant ascended and descended (10 steps 3 rounds). Peak plantar pressure was measured using Pedar X insole. The regional plantar pressure from the hallux, metatarsal 1-5, mid foot and heel was also analyzed. During stair ascending, the metatarsal heads and the hallux had higher peak plantar pressure compared to the stair descending. On the contrary, during the stair descending the hind foot had higher peak plantar pressure compared to stair ascending without TCO. The peak plantar pressure while using TCO was reduced dramatically compared to the shoe only condition. The plantar pressure distribution pattern was different for both stair ascending and descending activity. The TCO can effectively reduce the peak plantar pressure during stair ascending and stair descending.

Keywords*:* Diabetic feet; Stair walking; Total contact orthosis; Plantar pressure.

1. Introduction

Diabetic foot ulcerations and amputations are fearful complications related to diabetes and it has an adverse direct effect on the individual and also society [1]. The diabetic feet are at increased risk of ulceration because of the effects of diabetic pheripheral neuropathy. Diabetic foot ulceration is the results of several factors including poor sensation, biomechanical pressure and load trauma. An appropriate footwear and understanding of specific ambulatory activities may be useful for the prevention of plantar foot ulcers [2].

To date, most research works emphasis primarily on level walking, other activities such as stair ascending and descending which has yet to be studied in terms of plantar pressure distribution [3]. Increased range of motion is compulsory in order to perform the activity. It is predictable that callus formation under metatarsal heads interrupts the plantar pressure distribution. In clinical practice, clinicians try to redistribute the pressure and provide relief to the pressure sensitive regions where the chances of ulcerations are more, reduced through total contact orthosis (TCO) [4, 5]. The prescription of TCO is based on the hypothesis that excessive pressure lead to callus formation and ulceration under bony prominences.

In-shoe plantar pressure measuring system is being used frequently to obtain more precise information [6, 7]. Understanding of plantar pressure distribution and effectiveness of total contact orthosis in diabetic feet population will improve the clinical management of diabetic patients with foot complications. However, the relationship between plantar pressure and callus formation during stair walking is still unclear. The objectives of this study were to assess the differences regarding in-shoe plantar pressure in patients with diabetic feet during stair ascending and descending and to assess the effects of TCO in plantar pressure distribution

2. Methods

2.1 Subjects

Sixteen subjects were recruited from the primary care unit (PCU) at Songklanagarind hospital. The experimental protocol was approved by the human research ethical committee of faculty of medicine, Prince of Songkla University. Inclusion criteria were diabetes type II, age between 40 and 60 years, having callus or forefoot deformities as this group of subjects is most at risk of foot ulceration, unable to feel 5.07 Semmes-Weinstein monofilament and able to walk independently without supportive devices. Subjects with ulcers or Charcot's feet or any kind of amputations were excluded from the study. The patients were supplied with TCO and shoes. All subjects were informed about protocol and signed the informed consent form before participating in the study. Demographic details are shown in Table 1.

Table 1 Demographic data of subjects

Parameters	Mean	SD
No. of subjects	16 (8 Males, 8 Females)	
Age (year)	58	9
Height (cm)	157	8
Weight (kg)	74	14

2.2 Insole Preparation

The fabrication of TCO was done by certified prosthetist and orthotist in order to diminish the variation while modification. Foam impression was taken with the patient sitting with knee 90 degrees, neutral talus bone and controlled calcaneus bone without disturbing the medial arch. Positive molds were modified according to the blue ink footprints. The TCO were fabricated using individual positive plaster molds as shown in based on the foam impression taken at the time of casting as in Fig. 1. The TCO were adjusted and fitted into the patient's shoes and then patients were asked for discomfort feedback. All shoes had same heel height, to reduce the effect of the shoes on plantar pressure measurement as shown in Fig. 2.

Fig. 1 Fitted total contact orthosis.

Fig. 2 Sports shoe with heel height.

2.3 Plantar pressure Measurements

After the patients were fitted with TCO, the dynamic in-shoe plantar pressure measurement was recorded without and with TCO using Pedar® system (Novel GmbH, Munich, Germany) as shown in Fig. 3 (a), the insoles were placed between the socks and shoes. The Pedar® system has various sizes of flexible insoles with 99 sensors within each insole. The data acquisition rate was 100 Hz during the activity. The accuracy of Pedar® system insole measured with a resolution of 5 kPa that is the pressure range from 30 to 1200 kPa. The participants ascended and descended 10 steps (step height 17.5cm and 20.9 cm deep) for 3 rounds at self-selected speed with and without TCO as in Fig. 3 (b).

(a) (b)

Fig. 3 (a) Pedar® insoles fitted while participant wearing shoes, (b) Stair walking with and without TCO.

2.4 Data processing

Pedar Expert® software version 19.3.30 (Novel GmbH, Munich, Germany) was used to select consecutive 3 gait cycles from the raw data file. Four foot regions were focused as hind foot, mid-foot, forefoot and toes using Pedar Expert®.

2.5 Statistical Analysis

The descriptive statistics of plantar pressure was expressed as mean and standard deviations. Statistical analysis for plantar pressure was done using Prism 5.0 for Windows (GraphPad Software, San Diego, USA). A paired t-test was used to assess parameters derived from the plantar pressure measurements. The statistical significance of the test was set at $p<0.05$.

3. Results

The peak plantar pressure values during stair ascending and descending were significantly different between with and without TCO. With TCO condition, peak pressure was significantly affected in the toes and forefoot regions of the foot. There were significant difference of peak plantar pressure without TCO during stair ascending in the toes (216.71±7.03 kPa) and forefoot (275.15±2.81) while using TCO the plantar pressure reduction was significant at toes (158.35±7.89 kPa) and forefoot (218.59±2.34 kPa) regions of the foot as shown in Fig. 4.

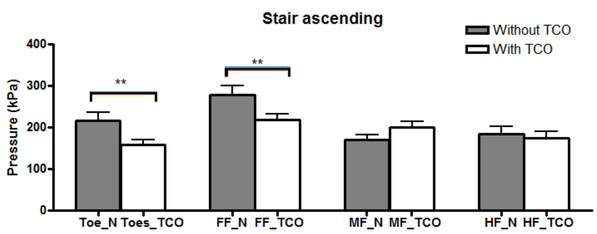

Fig. 4 The peak plantar pressure during stair ascending in two conditions of four plantar areas: toes (Toe), forefoot (FF), mid-foot (MF) and hind foot (HF). Significances between groups are displayed with ** ($p<0.01$). Values represent mean and standard error of mean (S.E.M.)

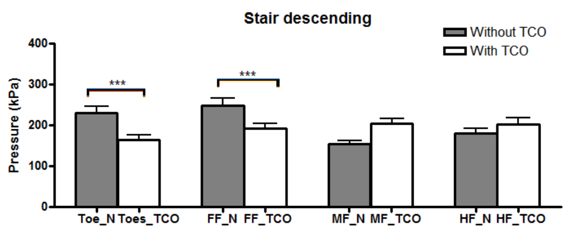

Fig. 5 The peak plantar pressure during stair descending in two conditions of four plantar areas: toes (Toe), forefoot (FF), mid-foot (MF) and hind foot (HF). Significances between groups are displayed with *** ($p< 0.001$). Values represent mean and standard error of mean (S.E.M.)

Furthermore, during stair descending without TCO the peak plantar pressure was higher at toes (229.53±19.06 kPa) and forefoot (248.52±4.14 kPa) whereas the significant differences in TCO condition were observed at toes (164.45±5.07 kPa) and forefoot (191.95±0.23 kPa) as shown in Fig. 5. However no significant differences were noticed in the mid-foot and the hind foot while using TCO.

4. Discussion

The most important findings of our study proved that TCO tend to reduce the plantar pressure by redistribution of pressure. The redistribution of plantar pressure while using TCO has an effect on the forefoot region which is in agreement with the previous results [7, 8]. The toes and forefoot regions of the foot have had higher plantar pressure during stair descending than stair ascending which was effectively reduced while using TCO [9]. The application of medial arch support TCO have widely used in order to maximize the surface area. The peak plantar pressure results showed that the TCO elevate the longitudinal arch of the foot hence increasing the plantar pressure at the mid-foot region and prevent it from the collapse of the medial arch of foot. Further studies are necessary to investigate the lateral and medial regions of the foot in order to design the effective TCO for patients who have diabetic feet.

5. Conclusion

Patients with diabetic feet who are at high risk for developing ulcers, total contact orthosis in a combination with stable shoes resulted in lower pressure at the forefoot and toe regions of the foot.

6. Acknowledgement

This study was financially supported by the Faculty of Medicine, Prince of Songkla University (58-161-20-2). The authors would like to thank the PCU for volunteer recruitment and the volunteers for their participation in the study.

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Appendix C

Ethics Approval

The result of Research Ethics Committee’s consideration, Faculty of Medicine, Prince of Songkla University.

VITAE

Name Muhammad Nouman

Student ID 5710320028

Educational Attainment

Degree	Name of Institution	Year of Graduation
Bachelor of Science (Prosthetics and Orthotics)	Mahidol University	2014

Scholarship Awards during Enrolment

- Thailand's Education Hub for ASEAN Countries (TEH-AC) scholarship award for Master's study during 2015-2016
- Graduate School dissertation funding for thesis
- Research Grant, Faculty of Medicine, Prince of Songkla University

Other Awards during Enrolment

- Best oral presentation for The 3rd Joint Symposium BMS-BME-EU: Post-graduate Health Science and Technology Conference 30th -31st May 2016, Faculty of Medicine, Prince of Songkla University, Thailand
- Best poster presentation for the 32nd Healthcare in a Changing World 3rd-5th August 2016, Faculty of Medicine, Prince of Songkla University, Thailand

List of Publication and Proceeding

Muhammad Nouman, Wipawan Leelasamran and Surapong Chatpun. Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic subjects during different walking activities (Submitted to Foot and Ankle International)

Muhammad Nouman, and Surapong Chatpun. The Role of Total Contact Orthosis on Plantar Pressure Distribution during Stair Walking in People with Diabetes. The 30th Conference of The Mechanical Engineering Network of Thailand 5th-8th July 2016, Songkhla, Thailand (Conference proceeding)