



UNIVERSITY OF TORONTO
LIBRARIES

 **CPOJ**
ISSN: 2561-987X

RESEARCH ARTICLE

Canadian Prosthetics & Orthotics Journal

All articles are permanently available online to the public without restrictions or subscription fees. They are free to be used, cited, and distributed, provided that appropriate acknowledgment is included. Authors retain the copyright of their original contributions and grant the Canadian Online Publication Group (COPG) a license to publish the article and identify itself as the original publisher. CPOJ articles are licensed under the Creative Commons Attribution 4.0 International License.

CPOJ Website: <https://jps.library.utoronto.ca/index.php/cpoj/index>

Editorial Office: cpoj@online-publication.com

ISSN: 2561-987X

CPOJ is a member of, and subscribes to the principles of, the Committee on Publication Ethics (COPE).



VOLUME 7, ISSUE 1

2024

Nouman M, Apiputhanayut R, Narungsri T, Tipchatyotin S, Dissaneewate T. Comparative analysis of three types of therapeutic offloading diabetic shoes with custom made insole on plantar pressure distribution in severe diabetic Charcot foot. Canadian Prosthetics & Orthotics Journal. 2024; Volume 7, Issue 1, No.3. <https://doi.org/10.33137/cpoj.v7i1.41780>

RESEARCH ARTICLE

COMPARATIVE ANALYSIS OF THREE TYPES OF THERAPEUTIC OFFLOADING DIABETIC SHOES WITH CUSTOM MADE INSOLE ON PLANTAR PRESSURE DISTRIBUTION IN SEVERE DIABETIC CHARCOT FOOT

Nouman M¹, Apiputhanayut R², Narungsri T³, Tipchatyotin S², Dissaneewate T²

¹ Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand.

² Department of Rehabilitation Medicine, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand.

³ Prosthetics and Orthotics Unit, Department of Rehabilitation Medicine, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand.

ABSTRACT

BACKGROUND: Charcot foot deformity, a severe complication of diabetes, involves neuropathy and abnormal peak plantar pressure in the midfoot and forefoot. However, orthotic interventions and shoe modifications are used to address the sequelae of Charcot neuroarthropathy, offering different approaches to managing abnormal peak plantar pressure.

OBJECTIVE: To compare the effects of three types of therapeutic offloading diabetic shoes; prefabricated, relasting, and double rocker-modified shoes on peak plantar pressure in the midfoot and forefoot of nonulcerated chronic Charcot foot during walking.

METHODOLOGY: A repeated measure design involved 15 participants (40% males and 60% females) with a mean age of 60.73 years (SD=10.50), with Charcot neuropathy. Participants were provided with three types of shoes; prefabricated, relasting, and double rocker-modified shoes, each equipped with the same custom-made insole (CMI). Plantar pressure was recorded while walking on level ground, focusing on the forefoot, midfoot, and hindfoot. The study also investigated additional variables affecting plantar pressure distribution, including the pressure-time integral and contact area.

FINDINGS: The type of shoe had distinct effects on the distribution of plantar pressure. The double rocker-modified shoe particularly impacted forefoot pressure during the terminal stance phase of the gait cycle. Peak plantar pressure at the forefoot increased by 5.37% with double rocker-modified shoes compared to relasting shoes. Both double rocker-modified and prefabricated shoes reduced midfoot peak plantar pressure by 8.73% and 11.97%, respectively. Similar trends were observed at the hindfoot, with reductions in peak plantar pressure. However, there were no significant differences in regional peak plantar pressure between the types of shoes except for the central forefoot ($F(1.61, 22.5) = 5.69$, $p = 0.014$).

CONCLUSION: There were no significant differences in the effectiveness of prefabricated, relasting, and double rocker-modified shoes in reducing and redistributing peak plantar pressure in high-risk areas of chronic Charcot foot.

ARTICLE INFO

Received: September 25, 2023

Accepted: July 30, 2024

Published: August 17, 2024

CITATION

Nouman M, Apiputhanayut R, Narungsri T, Tipchatyotin S, Dissaneewate T. Comparative analysis of three types of therapeutic offloading diabetic shoes with custom made insole on plantar pressure distribution in severe diabetic Charcot foot. *Canadian Prosthetics & Orthotics Journal*. 2024; Volume 7, Issue 1, No.3. <https://doi.org/10.33137/cpoj.v7i1.41780>

KEYWORDS

Neuroarthropathy, Therapeutic Shoe, Charcot Foot, Diabetic Foot, Plantar Pressure, Custom Made Insole, Orthotics, Orthosis, Gait

INTRODUCTION

Charcot neuropathic osteoarthropathy, also known as Charcot foot, is a serious complication that can result from any disorder associated with sensory or autonomic neuropathy. This complication leads to bone destruction, deformities, and ulcerations that can lead to amputation if

left untreated promptly and properly.¹ Charcot foot is a major cause of morbidity and mortality in people with diabetes, with a 5-year mortality rate of 29% for those with Charcot foot alone and up to 56.6% for those who have undergone major amputations.² Early diagnosis and treatment are crucial in preventing the progression of Charcot foot and minimizing the risk of complications. Charcot foot progresses through four stages: **stage 0**, characterized by asymptomatic or nonspecific symptoms and normal radiographs; **stage 1**, characterized by inflammation, swelling, and bone fragmentation visible on

* CORRESPONDING AUTHOR:

Tulaya Dissaneewate,

Department of Rehabilitation Medicine, Faculty of Medicine, Prince of Songkla University, Hatyai, Songkhla, Thailand.

E-mail: tulaya.p@psu.ac.th

ORCID ID: <https://orcid.org/0000-0003-2947-0375>

radiographs; **stage 2**, features decreasing inflammation and evidence of healing on radiographs.; and **stage 3**, noted for reduced swelling, joint stabilization, and new bone formation on radiographs. Each stage needs customized treatment approaches, emphasizing the importance of early recognition and appropriate management to prevent progression and complications.^{3,4} Treatment may involve immobilization, proper offloading devices, wound care, and surgery to repair or stabilize the affected foot.^{2,5}

According to the 2017 Global Burden of Disease Research, the cost of caring for diabetic foot diseases and their complications in the United States was estimated to be around \$237 billion.² At present, there is no offloading device guideline for chronic Charcot foot without plantar ulcer. Proper therapeutic footwear is recommended to remove high pressure sites and in severe cases it also promotes the healing process for Charcot foot with ulcer.^{6,7}

To prevent chronic Charcot foot ulceration, it is important to address gait dysfunction and biomechanical abnormalities that are common in people with diabetic neuropathic foot. These abnormalities often include an increase in the distribution of plantar pressure in sensitive areas. Notably, maintaining plantar pressure below the critical physiological skin tolerance level generally acknowledged to be less than 200 kPa to reduce the risk of developing foot ulceration and re-ulceration.⁸ The peak plantar pressure in Charcot foot mainly occurs in the midfoot area and redistribution of plantar foot pressure is considered the main method to reduce it. The footwear designs for redistributing midfoot peak plantar pressure are offloading pads, double rocker profile, proper shoe fitness, ankle-high, and knee-high offloading devices.^{9,10}

Double rocker modification of diabetic shoes uses the rocker-shaped sole in the shoe to help redistribute plantar pressure. There was a suggestion that the double rocker modification may be effective in offloading the peak plantar pressure at the deformed midfoot area in people with chronic Charcot foot.^{8,11} Currently, there is very limited literature that focuses on evaluating the effect of double rocker modification on the midfoot and forefoot area of chronic Charcot foot without plantar ulcer.

The extra width of the Charcot foot can also be a problem for shoe fitting, as it may cause improper foot pressure loading during gait. To address this issue, a relasting technique may be used to reduce and redistribute peak plantar pressure. Relasting shoes are recommended for people with foot deformities, arthritis, or other conditions that make it difficult to find proper shoes that fit comfortably.¹² The relasting technique requires reshaping the insole, outsole and heel of the shoe to better match the shape and size of the wearer's foot, which involves expanding the width of the shoe in the midfoot area to provide wider total contact of the plantar surface of the foot

with the shoe.^{13,14} However, to the author's knowledge, there is currently no research evaluating the effect of the relasting technique on midfoot peak plantar pressure of chronic Charcot foot without plantar foot ulcer. It was hypothesized that the relasting shoe with a custom-made insole (CMI) improves the offloading of the plantar aspect of the midfoot. Therefore, the aim of this study was to compare the effectiveness of prefabricated, relasting, and double rocker modified shoes to reduce and redistribute peak plantar pressure in the midfoot and forefoot in chronic Charcot without plantar ulcer. The outcome of this study may enhance the selection of suitable modified shoes to achieve optimal plantar pressure distribution, helping to prevent ulceration and re-ulceration in diabetic Charcot neuroarthropathy.

METHODOLOGY

Study population

Fifteen patients with Charcot neuroarthropathy were recruited from the Rehabilitation outpatient clinic, the Prosthetics and Orthotics clinic, the Diabetic clinic, and the Songklanagarind hospital inpatient department. Demographic characteristics including gender, body weight, height, shoe size, duration of diabetes, glycemic level, and foot-related problems were collected.

The type of foot was determined with the Foot Posture Index (FPI-6) by a clinician. FPI-6 is a clinical tool used to evaluate standing foot posture that provides a quantifiable measure, allowing clinicians to categorize foot types as supinated, neutral, or pronated. FPI-6 is widely recognized in clinical settings due to its reliability and ease of use, making it a valuable tool in both diagnostic and treatment planning processes for various foot-related conditions.^{15,16}

This project was approved by the Research Ethics Committee (REC.62-421-11-1), Faculty of Medicine, Prince of Songkla University.

The inclusion criteria for all participants were an age range 18 to 80 years old, unable to feel the 10-gram monofilament, and able to walk at least 10 meters without any aid at a self-selected speed. Participants were excluded if they had an active infected plantar foot wound, severe peripheral vascular disease, angina, dyspnea, major or minor lower limb amputation, and unstable vital signs. All participants signed written informed consent forms after understanding the whole experimental protocol.

Sample size determination

The sample size of 15 was determined to provide 80% probability of a clinically meaningful difference detection of 40 kPa in peak plantar pressure between footwear conditions. The standard deviation was set at 50 kPa and the alpha level was set at 0.05.¹⁷

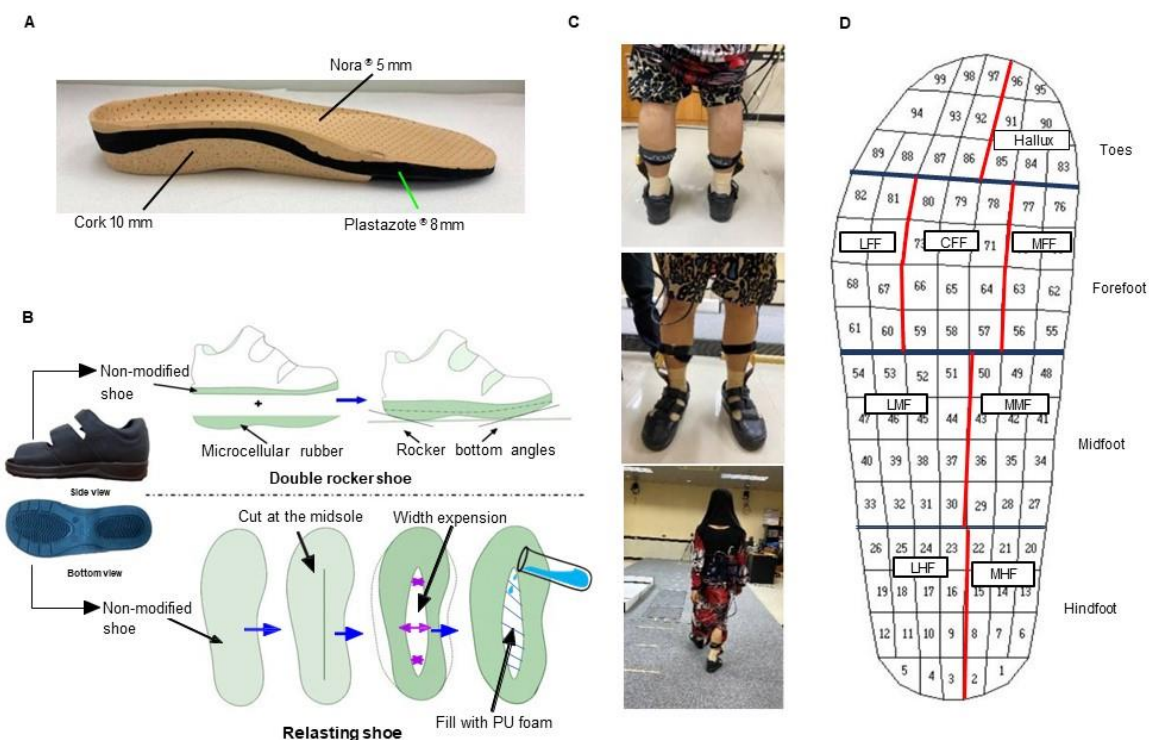


Figure 1: Charcot neuroarthropathic subjects are provided with a custom made insole (A), three types of shoes: prefabricated shoe; double rocker shoe, and relating shoes (B), with the data collected during gait (C) from three main regions of foot as hindfoot, midfoot, forefoot. The forefoot is subdivided into four regions as follows: lateral forefoot (LFF), central forefoot (CFF), medial forefoot (MFF) and hallux using masking software. The medial and lateral division is performed for the midfoot and the hindfoot (D).

Shoe and custom-made insole fabrication

A certified orthotist fabricated custom-made insoles (CMI) from Nora® 5 mm top layer, Plastazote® 8 mm middle layer, and cork 10 mm base layer (Figure 1-A). All patients received CMI with three footwear conditions, prefabricated shoes, double rocker shoes, and relating shoes. The design of the prefabricated shoes (CDM*: Cordoma International Co., Ltd.) are seamless lining with microcellular rubber outsole and a synthetic leather quarter. A certified orthotist modified the outsole of the prefabricated shoes with the addition of 10 mm ethylene vinyl acetate (EVA) 30 Shore A and reshaped it to make it a double rocker shoe with an angle of 10 degrees. Moreover, relating shoes are fabricated by cutting the middle of the shoes and adding polyurethane foam to provide more room for the midfoot in the mediolateral direction as shown in Figure 1-B. A 5 mm thick layer of anti-slip microcellular rubber with 70 Shore hardness was added to both double rocker and relating shoes, resisting wearing out and provide high stability.

* CDM is the brand of the prefabricated shoe used in this study.

Evaluation of plantar pressure

The peak plantar pressure was collected during gait with the Pedar-X® system (Novel Inc.; Munich, Germany), following the final fitting of the custom-made insole and three types of shoes. Data were collected from three gait cycles along a 10-meter walkway with self-selected speed. Before data collection, subjects walked along a 10-meter walkway at their comfortable speed to determine their walking speed and familiarize themselves with their shoes (Figure 1-C). The sensors were placed under CMI and each sensor was calibrated according to the guidelines. Novel Multimask software (Novel GmbH, Munich, Germany) was used to divide the foot area into 3 main regions, namely hindfoot, midfoot, and forefoot. The main three regions of the foot were divided into the medial hindfoot, lateral hindfoot, medial midfoot, lateral midfoot, medial forefoot, central forefoot, lateral forefoot, and big toe. Peak plantar pressure, pressure-time integral, contact area, and pressure mapping during gait were evaluated with three types of shoes. To evaluate the impact of shoes on plantar pressure distribution, each participant wore three types of shoes with the same CMI.

Data analysis

The data's descriptive statistics were presented as mean and standard deviation. Statistical analysis was performed using Prism 5.0 (GraphPad Software, San Diego, CA, USA). Analyses were conducted on the affected foot. A repeated measures ANOVA was used to compare plantar pressure and derived parameters among prefabricated, double rocker, and relasting shoes to assess the impact of shoe modifications. Post hoc comparisons were conducted where significant differences were found. Statistical significance was set at $p < 0.05$.

RESULTS

Participant characteristics

The participant demographics are shown in **Table 1**. Fifteen Charcot neuroarthropathic patients (6 (40%) males and 9 (60%) females) were included with a mean age of 60.73 (SD=10.5) years were included. The mean body mass index was 25.13 kg/m² (SD=2.52). Charcot foot cases represented a long duration of diabetes (16.33 years (SD=6.05)) related to poor glycemic control, and the serum HbA1c level was 7.88% (SD=0.85). The results also showed that 66.67% of patients with Charcot arthropathy had a history of previous foot problems, such as foot ulcers or surgery. Patients with stage 3 Charcot arthropathy in this

study showed a mean foot posture index (FPI-6) of 6.71 (SD=1.93).

Table 1: Demographic data of Charcot neuroarthropathic subjects.

Parameters	Mean	SD
Age (y)	60.73	10.50
Body weight (kg)	78.53	8.29
Height (m)	1.56	0.04
BMI (kg/m ²)	25.13	2.52
Shoe size (EU)	40.40	1.25
Duration of diabetes (y)	16.33	6.05
Serum HbA1C (% NGSP)	7.88	0.85
FPI-6	6.71	1.93

Regional peak plantar pressure

The midfoot showed higher peak plantar pressure with three types of shoes compared to the forefoot and hindfoot regions of the foot. Moreover, the tendency for the peak plantar pressure was higher in the lateral midfoot compared to the medial midfoot, as shown in **Figure 2**.

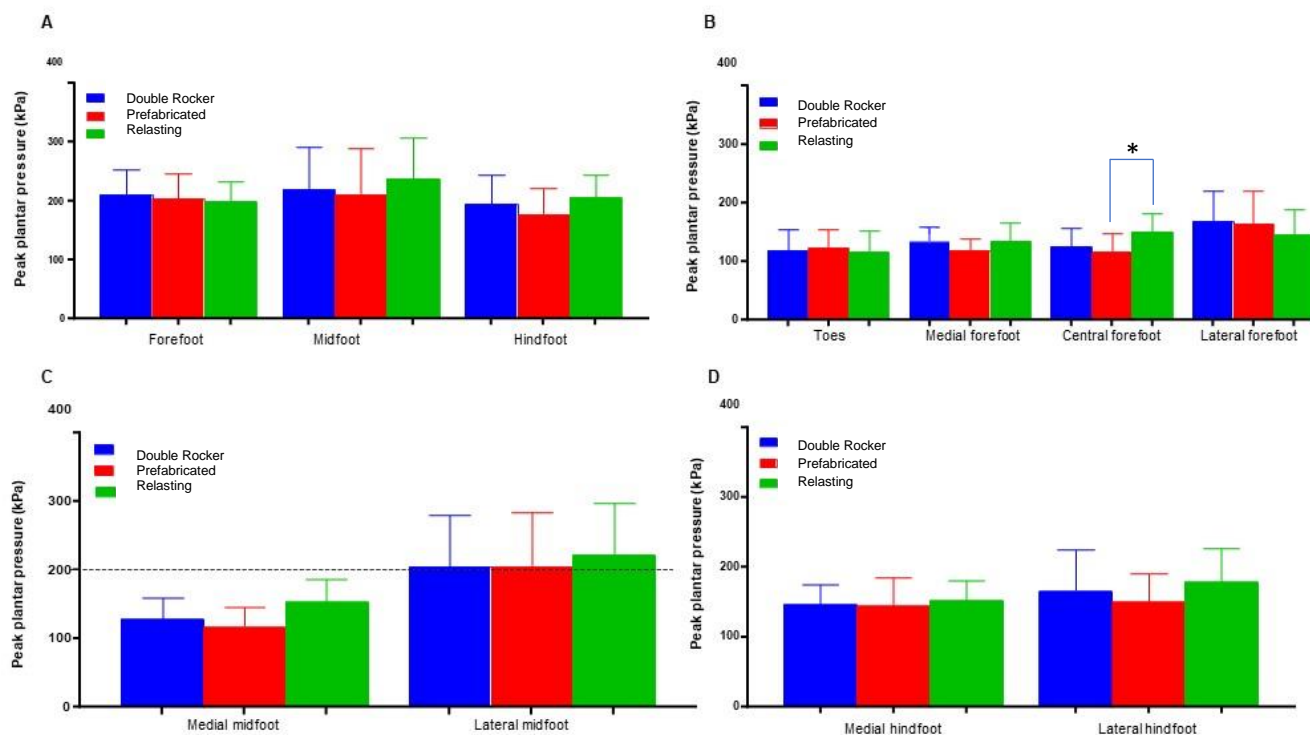


Figure 2: Peak plantar pressure during gait for three types of shoes—double rocker, prefabricated, and relasting—across different foot regions. The data is divided into: (A) Three main regions of the foot; (B) Four forefoot regions; (C) Two midfoot regions; (D) Two hindfoot regions. Significant differences are marked with an asterisk (*), indicating a p-value of less than 0.05.

The peak plantar pressure at the forefoot increased with double rocker-modified shoes compared to relasting shoes. Furthermore, the maximum plantar pressure was highest in the lateral forefoot with double rocker-modified shoes compared to relasting and prefabricated shoes. However, the central forefoot and medial forefoot peak plantar pressure is reduced with double rocker-modified shoes and prefabricated shoes (**Table 2**). There was no significant difference in regional peak plantar pressure among the measured variables except for the central forefoot with prefabricated and relasting shoes.

Regional pressure-time integral and contact area

The pressure-time integral and contact area from three regions of the foot are shown in **Table 3**. The pressure-time integral was highest at the midfoot compared to the forefoot and hindfoot using three types of shoes. The type of shoe has a minimum effect on the regional pressure-time integral.

The overall contact area among the foot regions increased in the forefoot with all types of shoes followed by the midfoot and the hindfoot.

Pressure mapping during gait

The pressure distribution across different phases of the gait cycle with various types of shoes reveals distinct patterns (**Figure 3**). Relasting shoes exhibit reduced pressure from initial contact to loading response. Moreover, during midstance, a similar trend can be observed with relasting and double rocker shoes, but the pressure increased in the lateral forefoot with prefabricated shoes. During terminal stance, double rocker shoes promote a more centralized pressure distribution. Conversely, prefabricated and relasting shoes resulted in higher lateral foot pressure.

Table 2: Regional peak plantar pressure with three types of shoes PF: prefabricated; DR: double rocker and RL: relasting from different regions of the foot.

Foot region	Shoe type comparison	Mean diff.	p-value	Geisser-Greenhouse's epsilon	r ²	F (DFn, DFd)
Forefoot	PF vs. DR	-6.60	0.609	0.818	0.047	0.69 (1.64, 22.90)
	RL vs. DR	-10.30	0.604			
	RL vs. PF	-3.65	0.910			
Toes	PF vs. DR	10.10	0.254	0.818	0.097	1.50 (1.64, 22.90)
	RL vs. DR	0.963	0.991			
	RL vs. PF	-9.09	0.219			
Medial forefoot	PF vs. DR	-9.99	0.391	0.860	0.100	1.56 (1.72, 24.10)
	RL vs. DR	2.86	0.894			
	RL vs. PF	12.90	0.352			
Central forefoot	PF vs. DR	-5.01	0.745	0.803	0.289	5.69 (1.61, 22.50)
	RL vs. DR	25.00	0.077			
	RL vs. PF	30.00	0.036 *			
Lateral forefoot	PF vs. DR	-5.74	0.822	0.961	0.187	3.21 (1.92, 26.90)
	RL vs. DR	-23.80	0.101			
	RL vs. PF	-18.10	0.149			
Midfoot	PF vs. DR	-6.97	0.867	0.895	0.158	2.62 (1.79, 25.00)
	RL vs. DR	19.80	0.154			
	RL vs. PF	26.80	0.115			
Medial midfoot	PF vs. DR	-10.60	0.707	0.930	0.197	3.44 (1.86, 26.00)
	RL vs. DR	25.40	0.161			
	RL vs. PF	36.00	0.095			
Lateral midfoot	PF vs. DR	-1.09	0.995	0.945	0.116	1.83 (1.89, 26.50)
	RL vs. DR	17.60	0.296			
	RL vs. PF	18.70	0.162			
Hind foot	PF vs. DR	-16.50	0.666	0.748	0.099	1.55 (1.50, 21.00)
	RL vs. DR	11.10	0.564			
	RL vs. PF	27.60	0.253			
Medial hindfoot	PF vs. DR	-1.74	0.990	0.665	0.014	0.21 (1.33, 18.60)
	RL vs. DR	5.91	0.687			
	RL vs. PF	7.65	0.873			
Lateral hindfoot	PF vs. DR	-16.40	0.580	0.919	0.133	2.16 (1.84, 25.70)
	RL vs. DR	13.00	0.577			
	RL vs. PF	29.40	0.107			

Table 3: Pressure-time integral and contact area with three types of shoes from three main regions of the foot during gait.

Foot region	Shoe type comparison	Mean diff.	p-value	Geisser-Greenhouse's epsilon	r ²	F (DFn, DFd)
Pressure-time integral						
Forefoot	PF vs. DR	-6.96	0.301	0.866	0.140	2.28 (1.73, 24.30)
	RL vs. DR	-10.80	0.210			
	RL vs. PF	-3.86	0.698			
Midfoot	PF vs. DR	-2.94	0.919	0.947	0.037	0.54 (1.89, 26.50)
	RL vs. DR	5.18	0.764			
	RL vs. PF	8.12	0.634			
Hind foot	PF vs. DR	-9.46	0.493	0.678	0.101	1.58(1.36, 19.00)
	RL vs. DR	2.87	0.767			
	RL vs. PF	12.30	0.357			
Contact area						
Forefoot	PF vs. DR	0.41	0.947	0.851	0.089	1.37 (1.70, 23.80)
	RL vs. DR	-1.43	0.513			
	RL vs. PF	-1.84	0.135			
Midfoot	PF vs. DR	2.29	0.275	0.971	0.159	2.64 (1.94, 27.20)
	RL vs. DR	-0.94	0.769			
	RL vs. PF	-3.22	0.132			
Hind foot	PF vs. DR	1.25	0.349	0.748	0.099	1.55 (1.50, 21.00)
	RL vs. DR	0.62	0.676			
	RL vs. PF	-0.63	0.675			

Note: PF: Prefabricated, DR: Double rocker, RL: Relasting

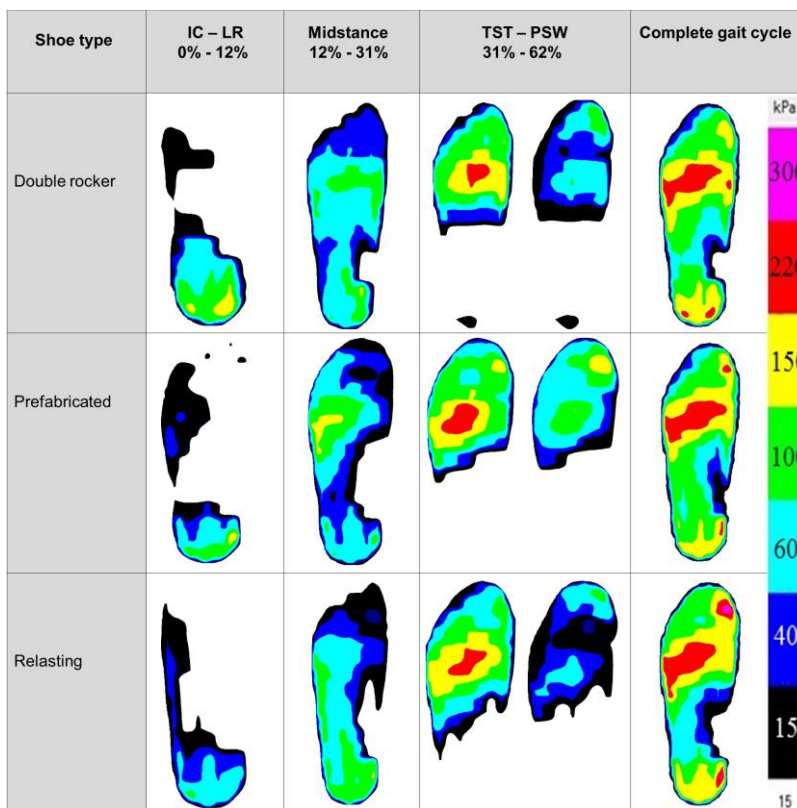


Figure 3: Pressure mapping during gait using double rocker, prefabricated, and relasting shoes. The data is shown for a single representative subject and includes: **IC – LR:** Initial Contact to Loading Response; **MST:** Midstance; **TST – PSW:** Terminal Stance to Pre-Swing.

DISCUSSION

This study found that relasting shoes increased the peak plantar pressure compared to prefabricated shoes and double rocker shoes at the central forefoot. However, opposite results were found in the lateral forefoot, as metatarsal heads are at high risk of ulceration and reulceration during gait. The peak plantar pressure was consistently less than 200 kPa with the modified shoes with custom-made insole at the medial midfoot and lateral midfoot, suggesting a potentially lower risk of ulceration in the midfoot region. These observations highlight the impact of shoe modifications on peak plantar pressure at specific regions, offering valuable insights into differential effects of various shoe types on foot pressure distribution.

Although the results did not reach statistical significance, they contribute to our understanding of how shoe modifications may affect plantar pressure distribution. The double rocker and prefabricated shoes demonstrated a reduction in peak plantar pressure in the midfoot and central forefoot areas compared to relasting shoes. This suggests a potential benefit in the offloading high-risk areas, which is critical to reduce the risk of ulceration.¹⁸

Shoe modification considering pathological foot biomechanics is one of the most common practices in normal clinical practice for Charcot neuroarthropathy.^{19,20} Shoe modifications, including rocker bottom outsoles, are effective in further reducing and redistribute peak plantar pressure in various foot complications.²¹ Rocker shoes provide a shorter contact time on heel strike and toe release, resulting in instability during gait in Charcot neuroarthropathy.²² However, relasting shoes that provide a wider mediolateral space for the foot to accommodate provide better stability during gait, but resulted in increased peak plantar pressure, especially at the forefoot and hallux compared to a double rocker shoe.²³

Researchers investigated double rocker shoes in reduction of hindfoot and forefoot peak plantar pressure, while preventing excessive overloading at the midfoot. During gait, shoes with rocker sole peak plantar pressure decreased especially in the forefoot regions but increased in the midfoot.²⁴ In this study, a similar pattern was observed in which there was a decrease in peak plantar pressure in both the forefoot and midfoot areas for patients with Charcot neuroarthropathy. The findings align with previous research that indicates that these areas are particularly vulnerable in the Charcot foot due to structural deformities and altered gait mechanics.^{16,25} The elevated pressure in these regions highlights the need for targeted interventions to better redistribute pressure during walking, particularly in the lateral midfoot and central to the medial forefoot.

Reducing peak plantar pressure while considering the importance of pressure-time integral to plantar ulceration, hence minimizing the combination of plantar pressure and the duration for which plantar pressure is applied to tissue, may be preferable than evaluating and reducing peak plantar pressure alone.²⁶ In this study, shoe modification impacts both peak plantar pressure and pressure-time integral outcomes in the forefoot and midfoot regions. Furthermore, the contact area in different foot regions did not show statistically significant differences. This suggests that the choice of shoe type with CMI may not significantly affect the contact area in specific foot regions.²⁷

There were several limitations while investigating the plantar pressure distribution among three types of therapeutic designs with CMI. The barefoot data was not included in this study due to the severity and potential to harm the plantar soft tissue during gait. The width dimension of the sensor insole could affect the accuracy of plantar pressure, especially in the midfoot, in Charcot neuroarthropathy. Only one type of rocker shoe was compared; however, other designs might be effective for populations facing severe foot complications. Further studies are required to evaluate the effectiveness of CMI and various shoe designs with varying rocker bottom sole angle and height on plantar pressure distribution in Charcot neuroarthropathy.

CONCLUSION

There were nonsignificant trends of pressure distribution and offloading in the high-risk areas of the foot using different types of shoe with CMI. Prefabricated and double rocker shoes showed some effectiveness in reducing peak plantar pressure in the midfoot, and central forefoot, compared to relasting shoes. However, achieving significant offloading in areas of high risk, such as the lateral midfoot, remains a challenge, which requires further shoe modifications and consideration of the materials and design of CMI. These insights are crucial for improving footwear interventions for diabetic Charcot neuroarthropathy, with the aim of reducing the risk of ulceration while maintaining foot functionality.

ACKNOWLEDGEMENTS

The authors would like to thank the Faculty of Medicine, Prince of Songkla University, for their financial support. We also extend our gratitude to the participants for their involvement in this study. Special thanks to Miss Phakatip Cheunchoksan for her assistance and to the Prosthetic and Orthotic Unit for providing the facilities.

DECLARATION OF CONFLICTING INTERESTS

The authors declare no potential conflict of interest.

AUTHORS CONTRIBUTION

Muhammad Nouman: Conceptualization, design, methodology, analysis, reviewing/revising manuscript, data interpretation.

Ravissada Apiputhanayut: Conceptualization, design, methodology, analysis, investigation, writing original draft, data interpretation, ethic certification application.

Tuanjit Narungsri: Conceptualization, methodology, reviewing/revising manuscript.

Suttipong Tipchatyotin: Conceptualization, supervision, methodology, reviewing/revising manuscript.

Tulaya Dissaneewate: Conceptualization, supervision, methodology, reviewing/revising manuscript, final manuscript approval.

All authors have read and approved the final version of the manuscript.

SOURCES OF SUPPORT

Faculty of Medicine, Prince of Songkla University, Songkhla Thailand.

REFERENCES

- 1.Das L, Rastogi A, Jude EB, Prakash M, Dutta P, Bhansali A. Long-term foot outcomes following differential abatement of inflammation and osteoclastogenesis for active Charcot neuroarthropathy in diabetes mellitus. *Plos One*. 2021;16(11):e0259224. DOI: 10.1371/journal.pone.0259224
- 2.Armstrong DG, Swerdlow MA, Armstrong AA, Conte MS, Padula WV, Bus SA. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. *J Foot Ankle Res*. 2020;13(1):16. DOI: 10.1186/s13047-020-00383-2
- 3.Jeffcoate WJ. Charcot foot syndrome. *Diabetic Med*. 2015;32(6):760-70. DOI: 10.1111/dme.12754
- 4.Rosenbaum AJ, DiPrea JA. Classifications in brief: Eichenholtz classification of Charcot arthropathy. *Clin Orthop Relat Res*. 2015;473(3):1168-71. DOI: 10.1007/s11999-014-4059-y
- 5.Crawford F, Chappell FM, Lewsey J, Riley R, Hawkins N, Nicolson D, et al. Risk assessments and structured care interventions for prevention of foot ulceration in diabetes: development and validation of a prognostic model. *Health Technol Assess*. 2020;24(62):1-198. DOI: 10.3310/hta24620
- 6.Zhang Y, Lazzarini PA, McPhail SM, van Netten JJ, Armstrong DG, Pacella RE. Global Disability Burdens of Diabetes-Related Lower-Extremity Complications in 1990 and 2016. *Diabetes Care*. 2020;43(5):964-74. DOI: 10.2337/dc19-1614
- 7.Wrobel JS, Najafi B. Diabetic foot biomechanics and gait dysfunction. *J Diabetes Sci Technol*. 2010;4(4):833-45. DOI: 10.1177/193229681000400411
- 8.Ahmed S, Barwick A, Butterworth P, Nancarrow S. Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review. *J Foot Ankle Res*. 2020;13(1):30. DOI: 10.1186/s13047-020-00400-4
- 9.Sawacha Z, Guarneri G, Cristoferi G, Guiotto A, Avogaro A, Cobelli C. Integrated kinematics-kinetics-plantar pressure data analysis: a useful tool for characterizing diabetic foot biomechanics.

Gait Posture. 2012;36(1):20-6. DOI: 10.1016/j.gaitpost.2011.12.007

10.Chatwin KE, Abbott CA, Boulton AJM, Bowling FL, Reeves ND. The role of foot pressure measurement in the prediction and prevention of diabetic foot ulceration-A comprehensive review. *Diabetes Metab Res Rev*. 2020;36(4):e3258. DOI: 10.1002/dmrr.3258

11.Janisse D, Janisse E. Pedorthic management of the diabetic foot. *Prosthet Orthot Int*. 2015 Feb;39(1):40-7. DOI:10.1177/0309364614535233

12.Janisse DJ, Janisse E. Shoe modification and the use of orthoses in the treatment of foot and ankle pathology. *J Am Acad Orthop Surg*. 2008;16(3):1528. DOI: 10.5435/00124635-200803000-00006

13.Zwaferink JBJ, Custers W, Paardekooper I, Berendsen HA, Bus SA. Optimizing footwear for the diabetic foot: Data-driven custom-made footwear concepts and their effect on pressure relief to prevent diabetic foot ulceration. *Plos One*. 2020;15(4):e0224010. DOI: 10.1371/journal.pone.0224010

14.Dahmen R, van der Wilden GJ, Lankhorst GJ, Boers M. Delphi process yielded consensus on terminology and research agenda for therapeutic footwear for neuropathic foot. *J Clin Epidemiol*. 2008;61(8):819-26. DOI: 10.1016/j.jclinepi.2007.09.003

15.Keukenkamp R, van Netten JJ, Busch-Westbroek TE, Nolle F, Bus SA. Users' needs and expectations and the design of a new custom-made indoor footwear solution for people with diabetes at risk of foot ulceration. *Disabil Rehabil*. 2021;1-8. DOI: 10.1080/09638288.2021.2003878

16.Redmond AC, Crosbie J, Ouvrier RA. Development and validation of a novel rating system for scoring standing foot posture: The Foot Posture Index. *Clin Biomech*. 2006;21(1):89-98. DOI: 10.1016/j.clinbiomech.2005.08.002

17.Hellstrand Tang U, Zügner R, Lisovskaja V, Karlsson J, Hagberg K, Tranberg R. Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers - A two-year, randomized trial. *J Clin Transl Endocrinol*. 2014 Dec 1;1(4):12132. DOI: 10.1016/j.jcte.2014.06.002

18.Bolglia LA, Malone TR. Plantar fasciitis and the windlass mechanism: A biomechanical link to clinical practice. *J Athl Training*. 2004;39(1):77-82.

19.Sangeorzan A, Sangeorzan B. Subtalar Joint Biomechanics: From Normal to Pathologic. *Foot Ankle Clin*. 2018;23(3):341-52. DOI: 10.1016/j.fcl.2018.04.002

20.Jastifer JR, Gustafson PA. The subtalar joint: biomechanics and functional representations in the literature. *Foot (Edinb)*. 2014;24(4):203-9. DOI: 10.1016/j.foot.2014.06.003

21.Fernando ME, Crowther RG, Cunningham M, Lazzarini PA, Sangla KS, Golledge J. Lower limb biomechanical characteristics of patients with neuropathic diabetic foot ulcers: the diabetes foot ulcer study protocol. *BMC Endocr Disord*. 2015;15:59. DOI: 10.1186/s12902-015-0057-7

22.Lopez-Moral M, Molines-Barroso RJ, Garcia-Morales E, Garcia-Alvarez Y, Alvaro-Afonso FJ, Lazaro-Martinez JL. Predictive values of foot plantar pressure assessment in patients with midfoot deformity secondary to Charcot neuroarthropathy. *Diabetes Res Clin Pract*. 2021;175:108795. DOI: 10.1016/j.diabres.2021.108795

23. Polomé E, Théveniau N, Vigier C, Dumas R, Robert T. Influence of different footwear on mediolateral stability during gait at different speeds in healthy people. *Comput Methods Biomech Biomed Engin.* 2020;23(sup1):S226-S8. DOI: 10.1080/10255842.2020.1815318
24. Arts MLJ, Waaijman R, de Haart M, Keukenkamp R, Nollet F, Bus SA. Offloading effect of therapeutic footwear in patients with diabetic neuropathy at high risk for plantar foot ulceration. *Diabetic Med.* 2012;29(12):1534-41. DOI: 10.1111/j.1464-5491.2012.03770.x
25. Bacarin TA, Sacco IC, Hennig EM. Plantar pressure distribution patterns during gait in diabetic neuropathy patients with a history of foot ulcers. *Clinics (Sao Paulo).* 2009;64(2):113-20. DOI: 10.1590/s1807-59322009000200008
26. Gerrard JM, Bonanno DR, Whittaker GA, Landorf KB. Effect of different orthotic materials on plantar pressures: a systematic review. *J Foot Ankle Res.* 2020;13(1):35. DOI: 10.1186/s13047-020-00401-3
27. Praet SFE, Louwerens J-WK. The Influence of Shoe Design on Plantar Pressures in Neuropathic Feet. *Diabetes Care.* 2003;26(2):441-5. DOI: 10.2337/diacare.26.2.441