ORIGINAL ARTICLE

Physical Therapy Journal of Indonesia (*PTJI*) 2026, Volume 7, Number 2: 202-207
E-ISSN : 2722-6034 ; P-ISSN : 2722-0125

Immediate effects on plantar pressure time integral with thermoplastic polyurethane versus plastazote insoles in type 2 diabetes with peripheral neuropathy: A randomized comparative study

Nyoman Chandra Adidharma[1,*], I Putu Alit Pawana[1,2], Lydia Arfianti[1], Inggar Narasinta[2], Sony Wibisono Mudjanarko[3], Atika[4], Fahrin Ramadan Andiwijaya[1]

[1]Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia
[2]Department of Physical Medicine and Rehabilitation, Dr. Soetomo General Academic Hospital, Surabaya, Indonesia
[3]Department of Internal Medicine and Rehabilitation, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia
[4]Department of Public Health and Preventive Medicine, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia

*Corresponding author:
Nyoman Chandra Adidharma; Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia;
adidharma20@gmail.com

Received: 2025-11-25
Accepted: 2026-03-20
Published: 2026-07-13

ABSTRACT

Background: The prevalence of diabetes continues to rise worldwide, and diabetic foot ulcers remain a serious complication caused by repeated pressure on the tissue of the sole of the foot due to neuropathy. This study aimed to compare the immediate changes in the plantar pressure time integral (PTI) following the use of Plastazote shoe insoles versus thermoplastic polyurethane (TPU) shoe insoles in adults with type 2 diabetes and peripheral neuropathy.

Methods: This study was a randomized, two-group pre-post design study. A total of 24 subjects with type 2 diabetes mellitus were divided into two groups of Plastazote insole group (n = 12) and the TPU insole group (n = 12). PTI was measured using a dynamic plantar pressure measurement system that divided the foot into five regions (heel, midfoot, forefoot, big toe, and toes) before and after insole use. Analyses were performed within groups (pre-post comparison) and between groups (ΔPTI comparison). Safety and user perception were evaluated using a pain VAS during insole use.

Results: TPU resulted in a greater reduction in PTI compared to Plastazote in the rear and middle sections of the foot ($p \leq 0.043$) as well as in total PTI ($p = 0.019$), while Plastazote increased PTI in the front section of the foot and total PTI ($p \leq 0.047$; $p < 0.001$). The between-group difference favored TPU ($p \leq 0.024$), with no effect on the big toe or other toes ($p \geq 0.721$).

Conclusion: In patients with type 2 diabetes, the highest plantar pressure is found in the heel and forefoot. The distribution of plantar pressure in type 2 diabetes is influenced more by dynamic factors and neuropathy than by static foot position. Therefore, screening for diabetic foot complications should incorporate static, dynamic, and sensorimotor assessments.

Keywords: diabetic foot ulcer, Plastazote, pressure time integral, thermoplastic polyurethane, type 2 diabetes mellitus.
Cite This Article: Adidharma, N.C., Pawana, I.P.A., Arfianti, L., Narasinta, I., Mudjanarko, S.W., Atika., Andiwijaya, F.R. 2026. Immediate effects on plantar pressure time integral with thermoplastic polyurethane versus plastazote insoles in type 2 diabetes with peripheral neuropathy: A randomized comparative study. *Physical Therapy Journal of Indonesia* 7(2): 202-207. DOI: 10.51559/ptji.v7i2.412

INTRODUCTION

Diabetes continues to rise globally, with recent estimates indicating hundreds of millions of adults living with the disease and a clear upward trend over recent decades.[1] The International Diabetes Federation reports that in 2024, there were 589 million adults (aged 20-79) living with diabetes, and this number is projected to continue rising through 2050.[2,3] The World Health Organization (WHO) also notes that the prevalence of diabetes among adults has risen from 7% (1990) to 14% (2022).[2]

One of the main complications of diabetes is diabetic foot ulcers, as this condition remains a leading cause of morbidity and mortality.[4] The International Working Group on Diabetic Foot emphasizes the importance of prevention through risk assessment, screening for neuropathy or peripheral artery disease, education, and the use of appropriate footwear or insoles to reduce mechanical pressure on the soles of the feet.[5]

The assessment of foot pressure inside shoes provides an objective method for measuring the extent to which therapeutic footwear and insoles affect foot pressure during actual walking while wearing shoes.[6,7] In this context, the pressure-time integral (PTI) reflects the cumulative pressure to which the plantar tissue is exposed over time during the stance phase and is commonly used as a marker of cumulative mechanical load.[8] PTI should be interpreted with caution, as this value is often closely correlated with peak pressure in many studies on footwear for people with diabetes. Therefore, its added value is most evident when it can explain specific mechanisms, such as the relationship between contact duration and pressure magnitude or improve the accuracy of predictions regarding relevant clinical outcomes.[9,10]

Therapeutic insoles are designed to reduce pressure on tissues by redistributing the load and increasing the effective contact area; however, the extent and regional patterns of load reduction depend heavily on the material properties and the overall construction of the insole.[11] Although both Plastazote and TPU are used in diabetic foot care, direct comparative evidence focusing on immediate PTI responses in a population of people with type 2 diabetes remains limited. This study aimed to compare immediate changes in regional and total PTI following the use of Plastazote versus TPU insoles in adults with type 2 diabetes and peripheral neuropathy.

METHODS

This study employed a two-group experimental design with pre-test and post-test measurements. The study population consisted of adults with type 2 diabetes who were receiving treatment at the endocrinology and/or medical rehabilitation outpatient clinics at Dr. Soetomo General Hospital in Surabaya. Sampling was conducted consecutively until the planned sample size was reached.

The inclusion criteria for this study were: diagnosis of type 2 diabetes according to the Indonesian Endocrinology Association Guidelines[12], peripheral neuropathy based on the Michigan Neuropathy Screening Instrument (MNSI) and International Working Group on the Diabetic Foot (IWGDF) ulcer risk category 0-1, age 18-59 years, normal cognitive function based on the Montreal Cognitive Assessment - Indonesian version (MOCA-Ina) score, BMI 18.5–24.9 kg/m², and the ability to walk independently without assistive devices. Exclusion criteria were acute infection/inflammation of the lower extremities, neuromusculoskeletal disorders affecting walking ability, abnormal resting vital signs (systolic blood pressure >140 and/or diastolic blood pressure >90 mmHg, heart rate >100/minute, temperature >37°C, SpO_2 <96%), and cardiopulmonary conditions affecting physical performance (e.g., New York Heart Association (NYHA) Class II–IV heart failure, angina, arrhythmia, persistent asthma, respiratory failure).

The total number of participants was 24, divided equally into two groups. Participants were randomly assigned to groups using Plastazote (**Figure 1a-b**) or TPU (**Figure 2a-b**) through simple randomization. The shoe soles were used only during the testing sessions; the use of the shoe soles and PTI measurements were conducted on the same day, with each test lasting approximately 10 minutes. Because the sole materials in the shoes differed visually and in texture, the participants and test operators could not be blinded. However, the results were evaluated in a blinded manner: PTI extraction and statistical analysis were performed on anonymized data sets labeled with group assignment codes.

PTI was assessed using the Pedar-X in-shoe system (novel GmbH, Germany).[13] The protocol specifies device characteristics (including sensor configuration and performance specifications) as well as standardized preparation procedures:

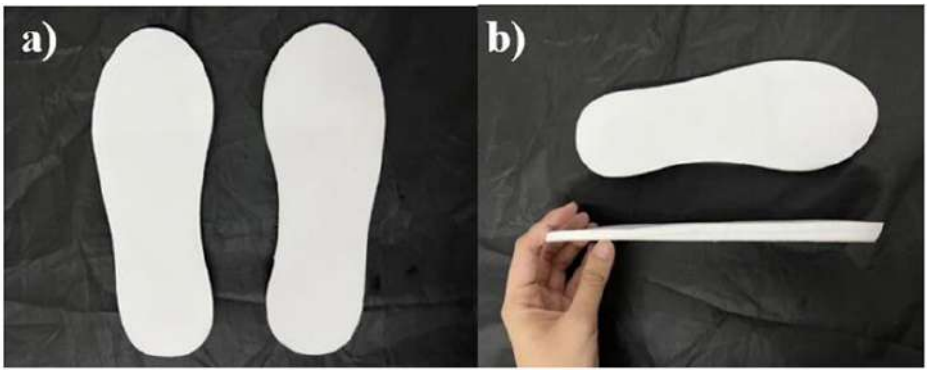

Figure 1a-b. Plastazote insole

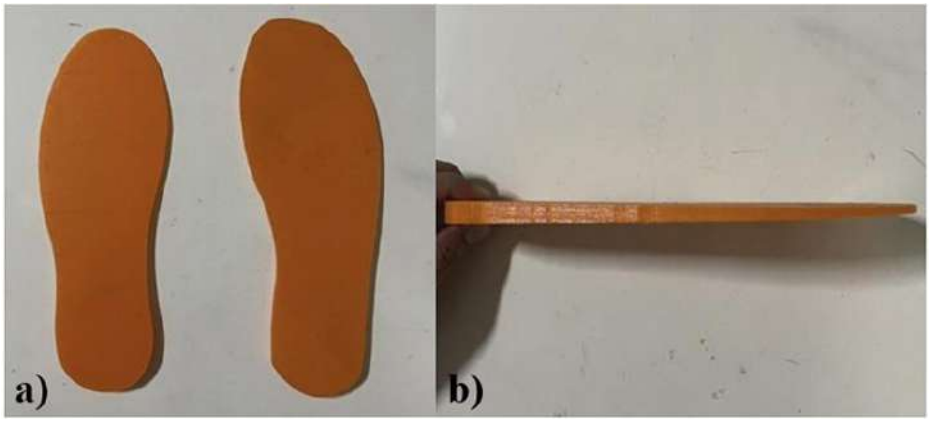

Figure 2a-b. Thermoplastic polyurethane (TPU) insole

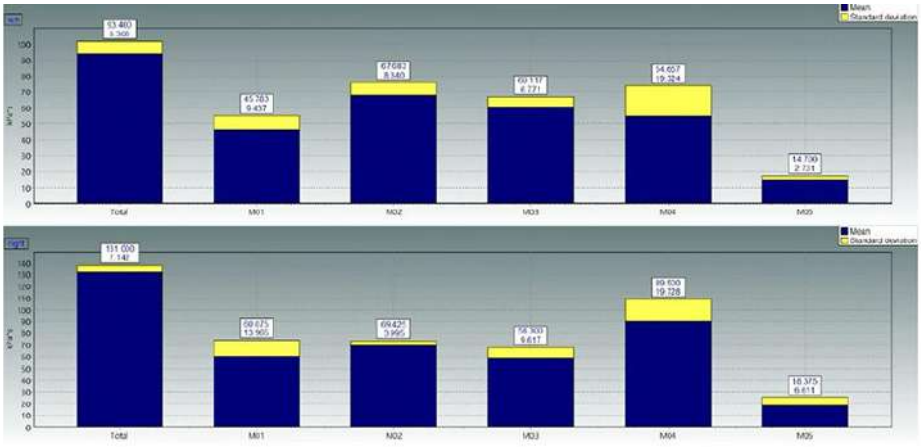

Figure 3. Cumulative five times pressure time integral (PTI) recording

feet are cleaned and dried without using lotion, participants wear thin socks, and appropriate athletic shoes that fit their foot size. Participants walked at a comfortable pace; step rhythm was aided by a metronome. PTI was recorded five times per condition without participants knowing the exact recording time to minimize changes in walking style (**Figure 3**). The primary outcomes were PTI (kilopascal-seconds (kPa·s,)) based on foot region (heel, midfoot, forefoot, big toe, toes) and total PTI (**Figure 4**).

Comparisons within groups (pre vs. post) were performed using a paired *t*-test if the parametric assumptions were met, or a Wilcoxon signed-rank test if not. Comparisons between groups regarding the dependent variable after the intervention and/or ΔPTI were performed using an independent *t*-test if the parametric assumptions were met, or a *Mann-Whitney* test if they were not. The significance threshold was set at $p < 0.05$.

Ethical approval was obtained from the Ethics Committee of Dr. Soetomo General Academic Hospital, Surabaya, Indonesia (registration ID: 1316/KEPK/V/2025). Written informed consent was obtained from all participants prior to enrollment, and the research procedures were conducted in accordance with the Declaration of Helsinki. We followed the CONSORT guidelines to the extent applicable in reporting this randomized controlled trial.[14]

RESULTS

The two groups were comparable at the start of the study. In the Plastazote group (n=12), the mean age was 53.4 years, with a balanced gender distribution (6 men, 50%; 6 women, 50%), while the TPU group (n=12) had a mean age of 52.1 years and was dominated by women (4 men, 34%; 8 women, 66%), with no statistically significant differences in age (p=0.52) or gender distribution (p=0.81). The mean BMI was 23.73 ± 2.61 kg/m² in the Plastazote group and 24.53 ± 1.99 kg/m² in the TPU group (p=0.41). The median duration of diabetes was 6.5 years (range 2–8) in the Plastazote group and 12 years (range 6–16) in the TPU group, which also did not differ significantly (p=0.25) (**Table 1**).

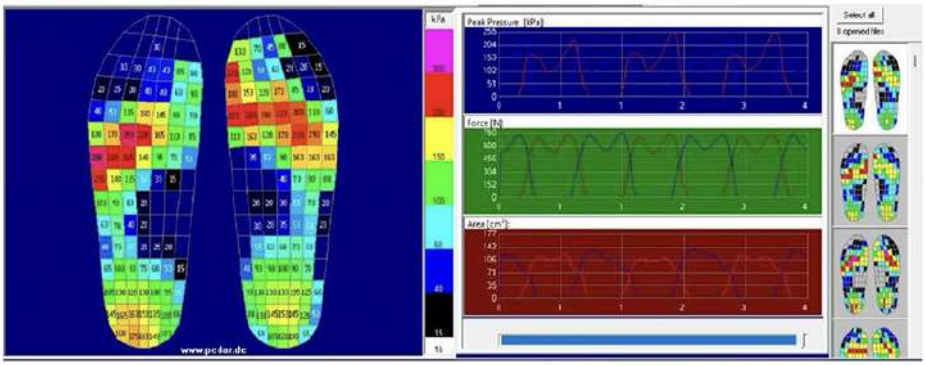

Figure 4. Pressure time integral (PTI) report

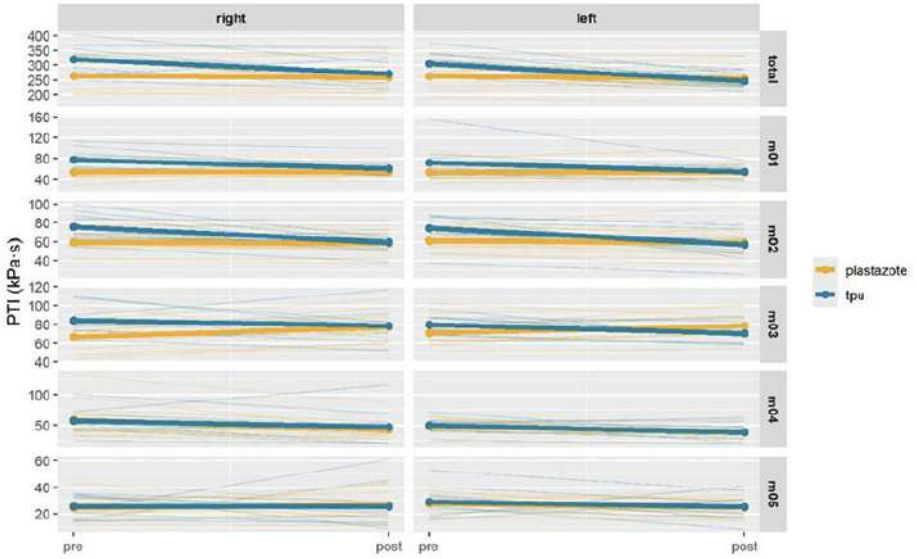

Figure 5. Pre-post changes in plantar pressure-time integral (PTI) for right and left feet. KPa.s, kilopascal-seconds; M01, hindfoot; M02, midfoot; M03, forefoot; M04, hallux; M05, toes; TPU, thermoplastic polyurethane.

Table 1. Baseline characteristics of both Plastazote and thermoplastic polyurethane groups

Characteristic	Plastazote (n=12)	TPU (n=12)	*P*-value
Age (years), mean	53.4	52.1	0.52
Sex, n (%)			0.81
Male	6 (50)	4 (34)	
Female	6 (50)	8 (66)	
BMI (kg/m²), mean ± SD	23.73 ± 2.61	24.53 ± 1.99	0.41
Diabetes duration (years), median (range)	6.5 (2–8)	12 (6–16)	0.25

Kg/m², kilogram per meter squared; n, frequency; SD, standard deviation; TPU, thermoplastic polyurethane.

On both feet, TPU produced a consistent and immediate reduction in PTI, particularly in the heel and midfoot regions, whereas Plastazote showed smaller changes and a tendency toward increased load in the forefoot region (**Figure 5**). For the right foot (**Table 2**), TPU significantly reduced PTI in the rearfoot region (Δ −16.35 ± 16.70; p=0.009) and the midfoot (Δ −16.22 ± 13.61; p=0.003), with a significant decrease in total PTI (Δ −14.14 ± 16.73; p=0.019). In contrast, Plastazote showed minimal changes in the rear and midfoot regions, as well as an increase

Table 2. **Plantar pressure-time integral (PTI, kPa.s) at pre-test, post-test, and change (Δ) across plantar regions and insole materials of the right foot.**

Region	Plastazote Pre (mean ± SD)	Plastazote Post (mean ± SD)	Plastazote Δ (mean ± SD), *P*-value (within)	TPU Pre (mean ± SD)	TPU Post (mean ± SD)	TPU Δ (mean ± SD), *P*-value (within)	Δ difference (TPU – Plast)	*P*-value (between Δ)
Hindfoot (M01)	54.61 ± 15.67	54.63 ± 11.52	0.02 ± 15.40, p=0.997	77.66 ± 19.70	61.31 ± 14.89	−16.35 ± 16.70, p=0.009	−16.37	0.024
Midfoot (M02)	59.44 ± 12.25	58.67 ± 12.37	−0.76 ± 7.78, p=0.740	75.62 ± 13.98	59.40 ± 11.34	−16.22 ± 13.61, p=0.003	−15.46	0.005
Forefoot (M03)	66.79 ± 16.78	77.07 ± 16.52	10.28 ± 15.91, p=0.047	83.98 ± 14.75	78.63 ± 16.54	−5.35 ± 16.77, p=0.315	−15.63	0.016
Hallux (M04)	58.67 ± 30.28	41.76 ± 17.20	−16.91 ± 18.17, p=0.008	56.94 ± 19.39	46.77 ± 27.76	−10.17 ± 21.97, p=0.156	6.74	0.976
Toes (M05)	26.77 ± 10.27	24.70 ± 8.89	2.07 ± 12.32, p=0.573	25.85 ± 8.49	25.49 ± 15.27	−0.36 ± 18.75, p=0.950	−2.43	0.721
Total PTI	101.63 ± 21.24	107.69 ± 21.35	6.06 ± 18.32, p=0.276	126.48 ± 20.80	112.34 ± 14.49	−14.14 ± 16.73, p=0.019	−20.20	0.012

SD, standard deviation; TPU, thermoplastic polyurethane.

Table 3. **Plantar pressure-time integral (PTI, kPa.s) at pre-test, post-test, and change (Δ) across plantar regions and insole materials of the left foot**

Region	Plastazote Pre (mean ± SD)	Plastazote Post (mean ± SD)	Plastazote Δ (mean ± SD), *P*-value (within)	TPU Pre (mean ± SD)	TPU Post (mean ± SD)	TPU Δ (mean ± SD), *P*-value (within)	Δ difference (TPU – Plast)	*P*-value (between Δ)
Hindfoot (M01)	54.56 ± 18.15	54.10 ± 19.68	−0.46 ± 24.56, p=0.949	72.45 ± 30.99	55.32 ± 11.60	−17.13 ± 24.56, p=0.043	−16.67	0.016
Midfoot (M02)	61.18 ± 11.21	58.77 ± 17.24	−2.41 ± 11.14, p=0.469	74.30 ± 14.07	56.97 ± 16.38	−17.33 ± 12.41, p<0.001	−14.92	0.007
Forefoot (M03)	71.02 ± 14.88	78.55 ± 14.92	7.53 ± 10.64, p=0.032	79.55 ± 9.81	70.56 ± 9.42	−8.99 ± 9.24, p=0.009	−16.52	0.001
Hallux (M04)	48.30 ± 11.59	38.10 ± 11.05	−10.20 ± 12.60, p=0.017	49.70 ± 11.77	38.77 ± 13.42	−10.93 ± 12.74, p=0.017	−0.73	0.890
Toes (M05)	27.55 ± 6.90	25.06 ± 7.96	−2.49 ± 9.17, p=0.367	28.98 ± 10.83	25.15 ± 9.71	−3.82 ± 14.10, p=0.390	−1.33	0.793
Total PTI	95.94 ± 16.58	111.21 ± 21.70	15.27 ± 9.59, p<0.001	117.30 ± 21.70	106.30 ± 12.76	−10.99 ± 18.92, p=0.083	−26.26	<0.001

SD, standard deviation; TPU, thermoplastic polyurethane.

in PTI in the forefoot region (Δ +10.28 ± 15.91; p=0.047). An inter-material comparison for Δ (TPU − plastazote) showed TPU's superiority in the rear of the foot (p=0.024), the midfoot (p=0.005), the forefoot (p=0.016), and total PTI (p=0.012), while there were no differences between the two materials in the big toe and toes (p=0.976 and p=0.721).

For the left foot (**Table 3**), TPU again resulted in a significant reduction in PTI in the heel region (Δ −17.13 ± 24.56; p=0.043), the midfoot region (Δ −17.33 ± 12.41; p<0.001), the forefoot region (Δ −8.99 ± 9.24; p=0.009), and the big toe (Δ −10.93 ± 12.74; p=0.017), with the total PTI reduction failing to reach significance in the group (Δ −10.99 ± 18.92; p=0.083). Plastazote, however, showed a significant increase in forefoot PTI (Δ +7.53 ± 10.64; p=0.032) and a significant increase in total PTI (Δ +15.27 ± 9.59; p<0.001). The between-group Δ comparison was highly favorable for TPU regarding the rear foot PTI (p=0.016), the midfoot (p=0.007), the forefoot (p=0.001), and total PTI (p<0.001), with no differences in the big toe or toes (p=0.890 and p=0.793).

DISCUSSION

This study shows that TPU soles result in a more significant reduction in PTI compared to Plastazote soles in adults with type 2 diabetes and peripheral neuropathy. There was a consistent reduction in the heel and midfoot areas, as well as a more favorable trend in total PTI. These findings are relevant for guideline-based prevention strategies that emphasize the reduction of mechanical pressure and the use of appropriate footwear/insoles for those at risk.[15–17]

An important clinical finding indicates that Plastazote insoles are associated with an increase in the plantar pressure index (PTI) in the forefoot (both feet) as well as an increase in the total PTI in the left foot.[15,16] Because the forefoot area, particularly beneath the metatarsal heads, is often the site of increased plantar pressure and plays a significant role in callus formation and the development of foot ulcers in neuropathy, any sudden shift toward increased cumulative pressure on the forefoot may be undesirable when the goal of prevention is to reduce pressure.[18–20]

Mechanically, PTI can increase due to higher pressure levels, longer contact times, or both. Under acute conditions, highly compliant materials can deform rapidly under the forefoot during the late stance and push-off phases, potentially altering rollover mechanics, prolonging regional contact time, or allowing local loading on bony prominences, which together may increase cumulative exposure even without significant changes in peak values. This interpretation aligns with the concept that PTI reflects both the magnitude and duration of the load and can be influenced by material behavior as well as how the sole modifies regional contact characteristics throughout the stance phase.[21]

At the same time, the interpretation of PTI requires nuance. PTI and peak pressure can behave similarly and be highly interdependent in diabetic footwear research, and a systematic review suggested limited incremental value of PTI reporting unless it improves prediction of ulceration beyond peak pressure.[9,10] In this manuscript, PTI remains the primary pre-specified outcome measure for the direct cumulative load response; however, future studies will be further strengthened by reporting peak pressure and contact area alongside PTI, as well as by linking these pressure metrics to clinical endpoints.[6,10]

Methodologically, the use of Pedar-X is supported by evidence regarding the reliability of results in assessing foot pressure inside shoes.[13] Our measurement approach (metronome-guided rhythm; repeated recordings without revealing the timing of data collection) was specifically designed to minimize changes in gait patterns and enhance measurement reliability. Previous evidence suggests that an adequate number of steps during the mid-gait phase can improve the validity and reliability of measurements in patients with diabetic neuropathy who use therapeutic footwear.[22]

This study has several limitations, including its acute research design and the fact that it was conducted in a single session; consequently, the results reflect only short-term biomechanical responses and cannot evaluate the durability of load reduction during repeated use or daily activities. The sample size was relatively small, limiting precision and subgroup analysis, and eligibility criteria restricted to BMI and age, thereby reducing generalizability to a broader population of people with diabetes. The results were limited to PTI during the controlled walking trial, with no parallel reports on peak pressure/contact area or objective gait parameters that could help interpret whether the changes were driven by pressure magnitude or contact time. Finally, this study did not evaluate clinical endpoints (calluses, pre-ulcer lesions, ulcer incidence/recurrence) or long-term safety, and the comparison of multiple regions per foot introduces a risk of multiplicity, thereby increasing the likelihood of false-positive findings.

Within the limitations of this single-session experiment, TPU produced a more consistent immediate reduction in PTI, suggesting that this material may be more suitable if the short-term goal is to reduce cumulative plantar load during walking, particularly in the proximal region and overall load. However, material selection in clinical practice must also consider comfort, durability, shoe sole compatibility, and whether load reduction is maintained during real-world walking volumes. Future studies should evaluate sustained use over days to months and assess material fatigue/decreased load-bearing capacity due to repetitive loading, integrate layered designs (e.g., an accommodative top layer with a supportive base), and perform iterative optimization using in-shoe pressure targets, reporting complementary metrics such as peak pressure, contact area, and spatio-temporal motion variables to clarify the mechanisms of PTI changes, and link biomechanical outcomes to clinically meaningful endpoints such as callus formation, pre-ulcer lesions, and ulcer incidence/recurrence in high-risk groups, in accordance with prevention guidelines.

CONCLUSION

In adults with type 2 diabetes and peripheral neuropathy, TPU shoe soles resulted in a more significant immediate reduction in PTI compared to Plastazote soles in several areas of the sole of the foot as well as in total PTI. The clinical impact

on ulcer prevention requires a longer follow-up period with additional clinical endpoints and plantar pressure metrics.

ETHICAL CONSIDERATIONS

Ethics approval was obtained from the Dr. Soetomo General Academic Hospital Ethics Committee (registration ID: 1316/KEPK/V/2025). Informed written consent was obtained from all participants prior to their enrollment, and the research procedures were conducted in accordance with the Declaration of Helsinki.

CONFLICT OF INTEREST

None

FUNDING

This study was entirely funded by the authors and did not receive any grants.

AUTHOR CONTRIBUTIONS

NCA and IPAP conceived the study design; NCA, IPAP, LA, IN, SWM, A, and FRA contributed in data collection and analysis, searched the literatures, and constructing and editing the manuscript.

REFERENCES

1. Zhou B, Rayner AW, Gregg EW, Sheffer KE, Carrillo-Larco RM, Bennett JE, et al. Worldwide trends in diabetes prevalence and treatment from 1990 to 2022: a pooled analysis of 1108 population-representative studies with 141 million participants. The Lancet. 2024; 404(10467): 2077-93.
2. Huang X, Wu Y, Ni Y, Xu H, He Y. Global, regional, and national burden of type 2 diabetes mellitus caused by high BMI from 1990 to 2021, and forecasts to 2045: analysis from the global burden of disease study 2021. Front Public Health. 2025; 13: 1-12.
3. Genitsaridi I, Salpea P, Salim A, Sajjadi SF, Tomic D, James S, et al. 11th edition of the IDF Diabetes Atlas: global, regional, and national diabetes prevalence estimates for 2024 and projections for 2050. Lancet Diabetes Endocrinol. 2026; 14(2): 149-56.
4. Edmonds M, Manu C, Vas P. The current burden of diabetic foot disease. J Clin Orthop Trauma. 2021; 17: 88-93.
5. Senneville É, Albalawi Z, van Asten SA, Abbas ZG, Allison G, Aragón-Sánchez J, et al. IWGDF/IDSA Guidelines on the Diagnosis and Treatment of Diabetes-related Foot Infections (IWGDF/IDSA 2023). Clinical Infectious Diseases. 2023: 1-23.
6. Bus SA, Valk GD, van Deursen RW, Armstrong DG, Caravaggi C, Hlaváček P, et al. The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: A systematic review. In: Diabetes/Metabolism Research and Reviews. 2008; 24(1): 162-80.
7. Lockhart M, Dinneen SF, O'Keeffe DT. Plantar pressure measurement in diabetic foot disease: A scoping review. Journal of Diabetes Investigation. John Wiley and Sons Inc; 2024: 15(8): 990-9.
8. Hulshof CM, van Netten JJ, Dekker MG, Pijnappels M, Bus SA. In-shoe plantar pressure depends on walking speed and type of weight-bearing activity in people with diabetes at high risk of foot ulceration. Clinical Biomechanics. 2023; 105: 1-10.
9. Waaijman R, Bus SA. The interdependency of peak pressure and pressure–time integral in pressure studies on diabetic footwear: No need to report both parameters. Gait Posture. 2012; 35(1): 1-5.
10. Bus SA, Waaijman R. The value of reporting pressure time integral data in addition to peak pressure data in studies on the diabetic foot: A systematic review. Clinical Biomechanics. 2013; 28(2): 117-21.
11. Nouman M, Dissaneewate T, Chong DYR, Chatpun S. Effects of custom-made insole materials on frictional stress and contact pressure in diabetic foot with neuropathy: Results from a finite element analysis. Applied Sciences (Switzerland). 2021; 11(8): 1-11.
12. Zhang J, Zhang Z, Zhang K, Ge X, Sun R, Zhai X. Early detection of type 2 diabetes risk: limitations of current diagnostic criteria. Front Endocrinol (Lausanne). 2023; 14: 1-7.
13. Ramanathan AK, Kiran P, Arnold GP, Wang W, Abboud RJ. Repeatability of the Pedar-X® in-shoe pressure measuring system. Foot and Ankle Surgery. 2010; 16(2): 70-3.
14. Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 statement: Updated guideline for reporting randomised trials. BMJ. 2025; 389: 1-8.
15. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. Diabetic foot disorders: A Clinical Practice Guideline. The journal foot & ankle surgery. 2006; 45(5): 1-66.
16. Pop-Busui R, Boulton AJM, Feldman EL, Bril V, Freeman R, Malik RA, et al. Diabetic neuropathy: A position statement by the American diabetes association. Diabetes Care. 2017; 40(1): 136-54.
17. Formosa C, Gatt A, Chockalingam N. A critical evaluation of existing diabetic foot screening guidelines. Review of Diabetic Studies. 2016; 13(2-3): 158-86.
18. Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, et al. Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. Diabetes Care. 1999; 22(1): 157-62.
19. Peters EJG, Armstrong DG, Lavery LA. Risk factors for recurrent diabetic foot ulcers: Site matters. Diabetes Care. 2007; 30(8): 2077-9.
20. Akkus G, Sert M. Diabetic foot ulcers: A devastating complication of diabetes mellitus continues non-stop in spite of new medical treatment modalities. World J Diabetes. 2022; 13(12): 1106-21.
21. Melai T, IJzerman TH, Schaper NC, de Lange TLH, Willems PJB, Meijer K, et al. Calculation of plantar pressure time integral, an alternative approach. Gait Posture. 2011; 34(3): 379-83.
22. Arts MLJ, Bus SA. Twelve steps per foot are recommended for valid and reliable in-shoe plantar pressure data in neuropathic diabetic patients wearing custom-made footwear. Clinical Biomechanics. 2011; 26(8): 880-4.