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Comparison of the Effects of Insoles Used in Diabetes Mellitus on Plantar Pressure: A Pilot Study

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Diabetes Mellitusda Kullanılan Kullanılan Tabanlıkların Ayak Taban Basıncı Üzerine Olan Etkileri Açısından Karşılaştırılması: Ön Çalışma

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Abstract

In individuals with diabetes reducing the contact pressure can significantly decrease the occurrence of ulcers of diabetic foot. The primary objective of this study was to ascertain the optimal characteristics of insole design that effectively alleviates pressure on the plantar foot. In this study, a comparative plantar pressure analysis was performed on four types of medical insoles such as silicone medical insoles with a universal fluid layer, customized three-layer medical insoles, flat silicone insoles, and prefabricate common silicone medical insoles using experimental data obtained through the PEDAR system in both standing and gait positions. The PEDAR system in gait condition findings indicate that silicone medical insoles with a universal fluid layer, customized three-layer medical insoles (Plastazote-Silicone- Ethylene Vinyl Acetate), flat silicone insoles, and prefabricate common silicone medical insoles reduce plantar pressure by 32%, 54%, 2.5%, and 6%, respectively, compared to without insoles condition. The PEDAR system findings during the stance phase, in conjunction with medical insoles, indicate that silicone medical insoles with a universal fluid layer, customized three-layer medical insoles, flat silicone insoles, and prefabricate common silicone medical insoles reduce plantar pressure by 30%, 75%, 6%, and 23%, respectively, compared to the without insoles condition. Evidence suggests that a universal medical insole is not suitable for all patients. Therefore, individual assessments are essential to identify insoles tailored to specific patient needs.

Keywords: *Medical insole; Diabetic insole; Plantar pressure; Pressure Redistribution*

Öz

Diyabetli bireylerde temas basıncının azaltılması, diyabetik ayak ülserlerinin oluşumunu önemli ölçüde azaltabilir. Bu çalışmanın temel amacı, ayak tabanındaki basıncı etkili bir şekilde azaltan tabanlık tasarımının en uygun özelliklerini belirlemektir. Bu çalışmada, PEDAR sistemi ile elde edilen deneysel veriler kullanılarak ayakta durma ve yürüme pozisyonlarında dört farklı tıbbi tabanlık türü üzerinde karşılaştırmalı ayak tabanı basıncı analizi yapılmıştır. Bu tabanlıklar; Üniversal sıvı katmanına sahip silikon tıbbi tabanlıklar, özelleştirilmiş üç katmanlı tıbbi tabanlıklar, düz silikon tabanlıklar ve fabrikasyon üretim yaygın silikon tıbbi tabanlıklardır. Yürüme koşullarında PEDAR sistemi bulguları, Üniversal sıvı katmanına sahip silikon tıbbi tabanlıkların, özelleştirilmiş üç katmanlı tıbbi tabanlıkların (Plastazot-Silikon-Etilen Vinil Asetat), düz silikon tabanlıkların ve fabrikasyon üretim yaygın silikon tıbbi tabanlıkların, tabanlık kullanılmayan duruma kıyasla plantar basıncı sırasıyla %32, %54, %2,5 ve %6 oranında azalttığını göstermektedir. PEDAR sistemi bulguları, duruş fazında tıbbi tabanlıklarla birlikte, Üniversal sıvı katmanına sahip silikon tıbbi tabanlıkların, özelleştirilmiş üç katmanlı tıbbi tabanlıkların, düz silikon tabanlıkların ve fabrikasyon üretim yaygın silikon tıbbi tabanlıkların plantar basıncı sırasıyla %30, %75, %6 ve %23 oranında azalttığını göstermektedir. Kanıtlar evrensel bir tıbbi tabanlığın tüm hastalar için uygun olmadığını göstermektedir. Bu nedenle, hastaların özel ihtiyaçlarına uygun tabanlıkları belirlemek için bireysel değerlendirmeler önemlidir.

Anahtar Kelimeler: *Tıbbi tabanlık; Diyabetik tabanlık; Plantar basınç; Basınç dağılımı*

1. Introduction

Diabetes poses a significant risk of morbidity and premature mortality, primarily attributed to chronic complications such as vascular, renal, retinal, or neuropathic disorders, as well as acute metabolic complications (Int. Ref.-1). Individuals who suffer from diabetic peripheral neuropathy may encounter difficulties related to their balance as a result of diminished somatosensory feedback. It is believed that approximately 50% of individuals diagnosed with diabetes will develop diabetic peripheral neuropathy within a span of 10 to 15 years (Cavanagh et al. 1993). Additionally, previous studies have unequivocally demonstrated a robust association between escalated plantar pressure and the onset of foot ulcers in individuals suffering from diabetic neuropathy (Tuna et al. 2014, Boulton, 2015, Greenman et al. 2005, Andreassen et al. 2009, Bacarin et al. 2009, Stokes et al. 2009, Caselli et al. 2002, Pham et al.

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2000, Waaijman and Bus, 2012). Patients diagnosed with diabetes have a lifetime risk of foot ulceration that can reach up to 25 percent, in comparison to healthy individuals who typically range from 4 to 10 percent (Lavery et al. 2003). There are various contributing factors to the formation of foot ulcers in individuals with diabetes. Specifically, an essential factor that significantly impacts ulcers on the plantar of their feet is the excessive pressure exerted on the soft tissue. To mitigate the occurrence of diabetic foot ulcers, it is essential to implement measures to reduce pressure below the critical threshold of 200 kPa (Bus et al. 2023). Pressure ulcers emerge as a result of a combination of both external and internal factors, with particular emphasis placed on external factors, particularly the pressures that give rise to skin and soft tissue ulcers. Notably, the non-vertical loading of soft tissue, encompassing shear and friction, is frequently highlighted as a fundamental element in the breakdown of the skin (Swain and Bader 2002, Edmonds, 2007, Turner et al. 2007, Kogani et al. 2015). Abnormal plantar pressure distribution along with its effects on soft tissue under bony prominences causes a prolonged high rate of ulceration due to neuropathy, limited joint mobility, and foot deformities in diabetic neuropathic feet (Gill et al. 2017, Fang et al. 2013). While plantar pressure is just one aspect of a comprehensive approach to preventing ulcer recurrence, the focus on reducing pressure in footwear is expected to produce favorable outcomes. A schematic illustrating the diabetic foot and the injuries associated with diabetic neuropathy is presented in Figure 1.

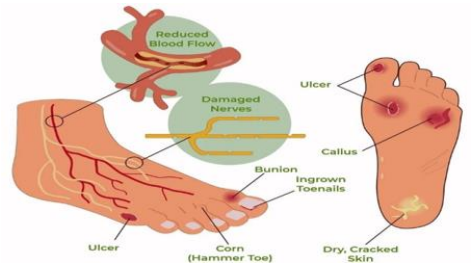

Figure 1. Diabetic foot ulcers and neuropathy (Int. Ref.-2).

Based on research conducted in the area of diabetic foot ulcers and pressure distribution on the diabetic foot, it can be deduced that the utilization of medical shoes and insoles is a viable and economically feasible approach for the prevention or amelioration of diabetic foot ulcers (Caravaggi, et al. 20, Mattila, et al. 2011, O'Leary et al. 2008) and it has been observed that insoles not only offer immediate but also long-term protection against foot ulcers (Speed et al. 2018, van Netten et al. 2018, Zulkifli and Loh 2020, McCartan and Rosenblum, 2014). As a consequence, the identification and mapping of areas with elevated plantar pressure are utilized to inform the development of footwear and insoles that aim to mitigate pressure in these regions (Bus et al. 2011, Collings et al, 2021, Ahmed et al. 2020). The big toe, metatarsal heads, midfoot, and hindfoot are the most frequent sites prone to deformities as well as ulcers (Boulton et al. 1987, Nouman et al. 2017).

Several studies have measured and compared plantar pressure in individuals with diabetes to that in healthy people's plantar pressure in order to obtain a comprehensive understanding of the differences between the two groups (Caselli et al. 2002, Sinacore et al. 2008, Abri et al. 2019, Cao et al. 2022, Syed et al. 2013, Ahsan et al. 2021, Zimny et al. 2004, Caravaggi et al. 2017, Searle et al. 2018, Robinson et al. 2013). Almost all previous studies on the design and manufacturing of diabetic footwear have focused on obtaining foot pressure measurements both before and after the utilization of the designed footwear Additionally, this study involves a comparative analysis of various types of footwear (Chang et al. 2014, Lo et al. 2015, Nunns et al. 2016, Mossayebi et al. 2015, Tsung et al. 2004, Shakouri et al. 2020, Safaeepour et al. 2021, Prasetyanto et al. 2021, Ghassemi et al. 2015, Van Geffen et al. 2007, Owings et al. 2008). Custom-made insoles have traditionally been used to reduce peak pressure by maximizing the total plantar contact area (Bus et al. 2004). However, this approach may not adequately address the underlying biomechanical foot dysfunction that often accompanies diabetic neuropathy. Such dysfunction affects the distribution of plantar loads and the mechanical stress on tissues (Mueller et al. 2003, Morag and Cavanagh, 1999). A more functional approach to insole design could potentially have a greater impact on minimizing the effects of altered foot biomechanics. That's why some articles (Caravaggi et al. 2016, Tsung et al. 2004) explain the benefits of customized insoles which are produced based on the contour of individual feet and are more effective at reducing peak pressure than basic insoles but, some articles (Paton et al. 2012) stated that custom-made insoles are more expensive than prefabricated insoles evaluated in this trial and are no better at reducing peak pressure. they recommend that where clinically appropriate, the more cost-effective prefabricated insole should be considered for use by patients with diabetes and neuropathy.

This study aimed to evaluate the pressure reduction on the plantar foot when using silicone medical insoles with a universal fluid layer (SIF), customized three-layer medical insoles (CTI), flat silicone insoles (FSI), and prefabricate common silicone medical insoles (PSI) insoles in comparison to the pressure experienced without any insoles. Custom-made insoles provide

superior comfort and alleviate pressure more effectively than flat insoles. However, the processes involved in creating these custom insoles—such as scanning, design, and machining—can be time-consuming and costly. When the primary requirement is simply to match the foot arch, without the need for specialized accessories or varying angles, the traditional custom insole manufacturing process may be unnecessary. Instead, silicone insoles with a universal fluid layer can adaptively conform to the arch of the foot, offering a customized fit without the significant time and financial investments. These medical insoles utilize the fluid's mobility to deliver natural massages to the plantar region, making them particularly beneficial for the general population, including diabetic patients and athletes, as supported by further studies. Specifically, this research seeks to thoroughly investigate the efficacy of insoles containing a fluid layer in relation to other medical insoles specifically designed for individuals with diabetes. The objective is to demonstrate how this particular type of insole can effectively reduce plantar pressure compared to alternative insoles.

2. Materials and Methods

As stated in the article by Shakouri et al (2020), the insole incorporates a universal fluid middle layer composed of silicone gel, as illustrated in Figure 2.

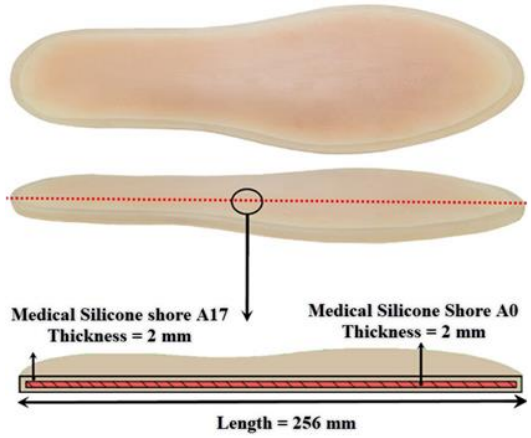

Figure 2. The fabricated silicone insole with the universal fluid layer and a view of its cutoff model (Shakouri et al. 2020).

Following the fabrication of silicone with a Shore A hardness of 17, a hardness test was conducted utilizing a polymer Shore durometer (Zwick Shore Durometer Tester Close-up SR: 7206.07/00) by the ASTM D2240 standard to verify the degree of hardness. To determine the mechanical properties of the silicone, a uniaxial compression test was executed using a Hiwa200 material testing device (Korea, Sales@hiwa.cn) in compliance with the ASTM D575 standard. The resultant stress-strain curve for the silicone is presented in Figure 3.

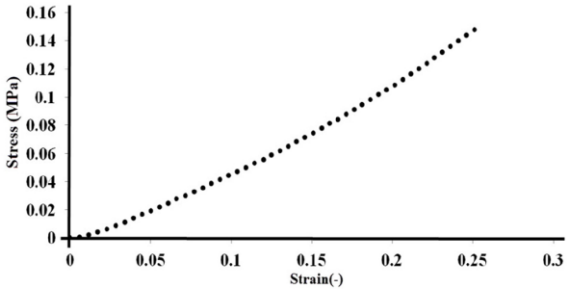

Figure 3. The stress-strain curve of the silicone shore A17 used in the medical insole.

Note that the silicone gel code was 9405 according to the technical information presented by the manufacturer company (Shenzhen Company in China) and its viscosity has been reported as 1500 mPa.s. This insole is flat and has a thickness of 6 mm. It consists of Silicone gel, with a fluid layer thickness of 2 mm, incorporating Shore A0 as a material. This material is sandwiched between two layers of silicone, each with a thickness of 2 mm, using Shore A17 as the material. This insole is manufactured through a combination of molding and ultrasonic welding techniques. Subsequently, silicone gel with a Shore A0 has been injected between the two layers of silicone with a Shore A17.

The other insole (Safaeepour et al. 2021) was characterized as a flat insole with identical dimensions to the has fluid layer insole; however, it was constructed from medical-grade silicone with a Shore A17 and did not contain any gel in its central region.

In another study (Ghassemi et al. 2015), a comparison was conducted between customized single-layer and CTI under static and dynamic loading conditions. Silicone gel (SG), Plastazote foam (PLZ), polyfoam (PF), and ethyl vinyl acetate foam (EVA) were chosen as the selected materials. Four single-layer insoles and 18 combinations of three-layer insoles were chosen for analysis. In this article, the most favorable outcome from Ghassemi's study was utilized, specifically the three-layer composition of the Plastazote-Silicone-EVA insole. CTI is shown in Figure 4.

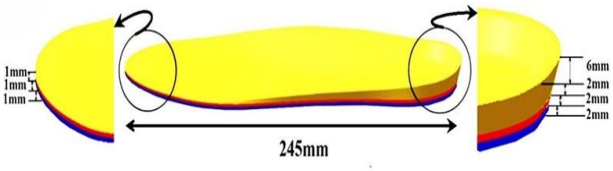

Figure 4. Insoles in CATIA Software. three-layer insole (Ghassemi et al. 2015).

This customized insole is produced using a CNC machine, and the plantar surface of diabetic patients' feet was scanned using a three-dimensional scanner (Shoe Master Custom System, Torielli, Italy, www.torielli.com). This data was then transmitted to a CNC machine (ECOPLAN

CNC Milling Machine 03 406-E, Torielli, Italy, www.torielli.com) to mill the foam according to the geometry of the plantar surface. In the construction of a three-layered insole, the first layer was machined to the appropriate thickness using the CNC machine. Subsequently, the layers were adhered to using a specialized adhesive. For the silicone layers, liquid silicone was molded using a prefabricated die. The process of fabricating custom insoles is illustrated in Figure 5.

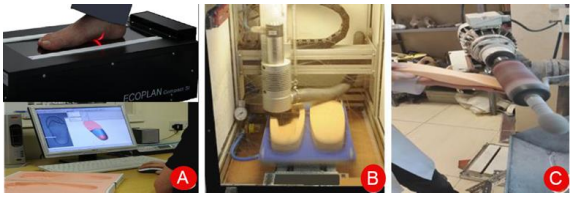

Figure 5. The steps of making customized insoles: A) Scanning the foot and designing the insoles in accordance with the arc of the individual's foot; B) Transferring data to the CNC machine; C) Completing the finishing and Laboring processes.

A commonly used silicone insole, which is produced in a pre-fabricated form, was chosen based on the following specifications:

Depth 8 mm, Height 245 mm, Width 85 mm, Net weight 0.17 kg, and Main body material Silicone Shore 20A, blue part Shore 8A. PSI is shown in Figure 6. As all of the studies presented in this work were designed as pilot studies, only one participant was included in each study. The purpose was to evaluate the feasibility and functionality of the insole assessment methods before proceeding to a larger-scale study. The personal characteristics of the testers are listed in Table 1.

Figure 6. A common silicone insole.

Table 1. Individual profile.

Ref.	Sex	Weight	Age	Condition
Shakouri et al. 2020	Male	95 kg	25	A healthy person without any foot complications
Ghassemi et al. 2015	Male	95 kg	30	Diabetic person without neuropathy and foot ulcer
Safaeepour et al. 2012	Male	90 kg	31	A healthy person without any foot complications
PSI	Male	95 kg	30	A healthy person without any foot complications

The PEDAR system comprises two thin insoles, each equipped with 99 sensors, which are positioned within the shoes and on the soles of the tested shoes. Initially, the straw-shaped sensor insoles underwent a calibration process, during which they were connected to a computer via a cable. The calibration procedure involved elevating the right foot while the left foot remained in contact with the ground. Following the identification of the left foot and the zeroing of the plantar pressures of the right foot, this process was subsequently repeated for the contralateral foot. Upon completion of the calibration, both dynamic (walking) and static (standing) tests were conducted; these were performed first without an orthosis and then subsequently with various custom-made orthotic devices.

3. Experimental Result

The output results obtained from the PEDAR system in dynamic mode (Gait) for four specifics selected category types are presented in Table 2. Also, the plantar pressure in each region was compared separately in Figure 7-14. For dynamic tests, the participant walked on a 10 meter walkway.

Table 2. The results of the PEDAR system in dynamic mode (gait) with and without insoles (WI).

	Shakouri et al. 2020		Ghassemi et al. 2015		Safaeepour et al. 2021		PSI	
Prescribed locations	WI (kPa)	SIF (kPa)	WI (kPa)	CTI (P-S-E) (kPa)	WI (kPa)	FSI (kPa)	WI (kPa)	PSI (kPa)
Hallux	321	138	161	107	270	227	317	326
Toe 2-5	64	189.5	87	31	47	42.5	60	81
Metatarsal 1	306	146	326	127	197	165	310.5	218
Metatarsal 2	164.5	146.5	223	98	193	166	165	176
Metatarsal 3-5	178	42	165	74	40	141.5	180.5	167
Lateral arc	155	50	90	62	113	103	155	35
Medial arc	25	100	47	34	11	12	23.5	129.5
Heel	165	131	192.5	50	144	131	170	166.5

WI: Without Insoles, SIF: Silicone Medical Insoles with a Universal Fluid Layer, CTI: Flat Silicone Insoles, PSI: Prefabricate Common Silicone Medical Insoles.

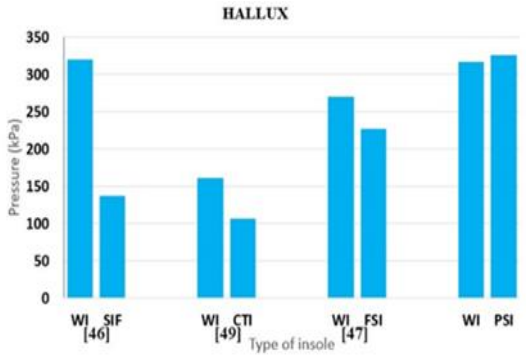

Figure 7. Comparison of pressure in the Hallux region during gait, with and without (WI) medical insoles.

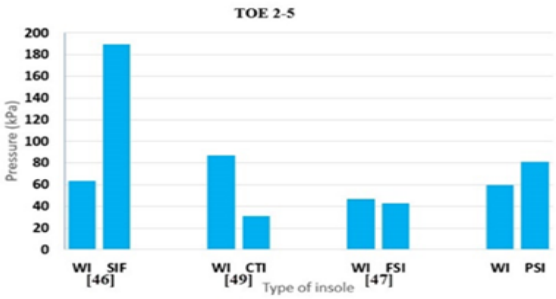

Figure 8. Comparison of pressure in the Toe 2-5 region during gait, with and without (WI) medical insoles.

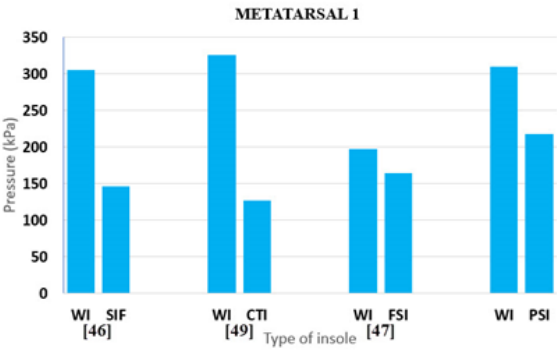

Figure 9. Comparison of pressure in the Metatarsal 1 region during gait, with and without (WI) medical insoles.

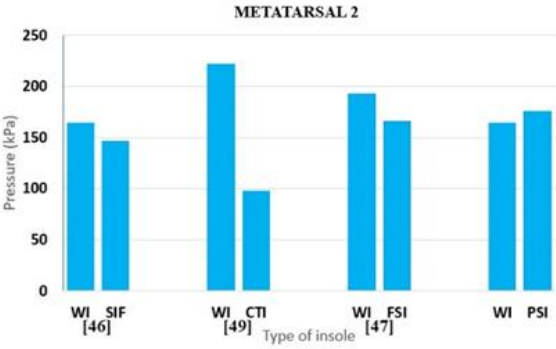

Figure 10. Comparison of pressure in the Metatarsal 2 region during gait, with and without (WI) medical insoles.

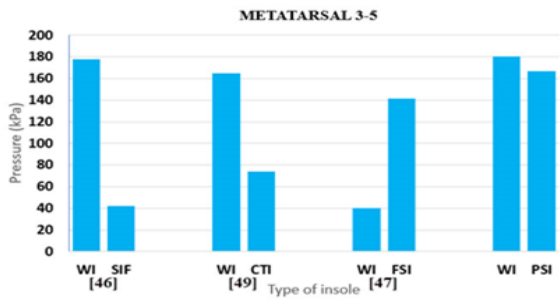

Figure 11. Comparison of pressure in the Metatarsal 3-5 region during gait, with and without (WI) medical insoles.

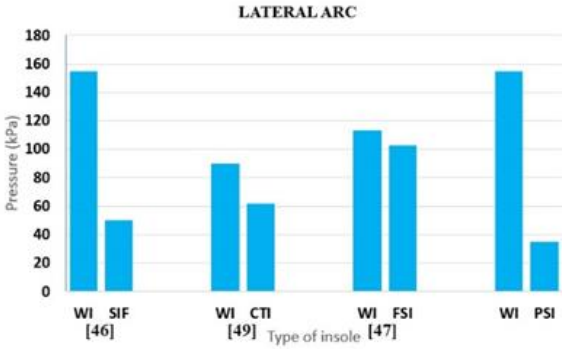

Figure 12. Comparison of pressure in the Lateral arc region during gait, with and without (WI) medical insoles.

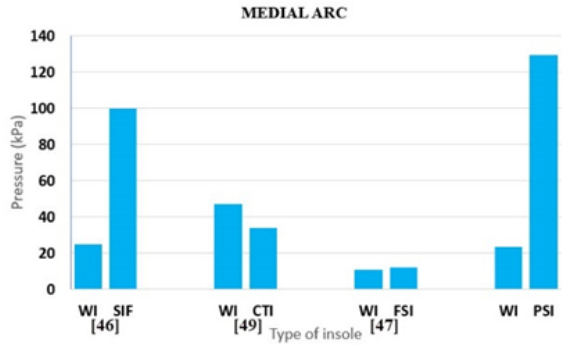

Figure 13. Comparison of pressure in the Medial arc region during gait, with and without (WI) medical insoles.

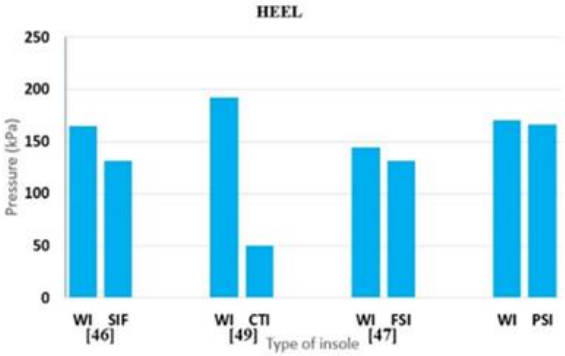

Figure 14. Comparison of pressure in the Heel region during gait, with and without (WI) medical insoles.

The findings from the PEDAR system, dynamic condition and without medical insoles, indicate that the highest plantar pressure is observed in the hallux and the first metatarsal region. Conversely, the medial mid-arc and the second to fifth toes exposure to the lowest pressure in this condition.

The findings obtained from the PEDAR system, in conjunction with medical insoles, indicate that SIF, CTI, FSI, and PSI yield reductions in plantar pressure of 32%, 54%, 2.5%, and 6%, respectively, compared to the without of utilizing any insoles. SIF, CTI, and FSI by 57%, 33.5%, and 16%, respectively, in the high-risk area of the hallux and the high-risk area of the first metatarsal, the 52%, 61%, and 16.5% respectively decrease plantar pressure. Meanwhile, the pressure in the hallux has experienced a 3% increase when using PSI.

The findings obtained from the PEDAR system indicate that the SIF effectively redistributes pressure by facilitating fluid movement during walking. Consequently, this redistribution results in an increase of 66% and 75% in pressure levels within the toe 2-5 areas; and the medial middle region of the foot, respectively. These areas are commonly recognized as low-pressure areas in previous studies, thus exemplifying the efficacy of the insole in redistributing pressure from high-pressure areas to these low-pressure regions.

The results obtained from the PEDAR system reveal that the utilization of PSI has resulted in a rise in excessive pressure within the high-pressure regions of the foot, namely the hallux and the second metatarsal. Specifically, the pressure in these aforementioned areas has exhibited an increase of 3% and 6%, respectively.

The output results obtained from the PEDAR system in static mode (stance) for four specific selected category types are presented in Table 3. Also, the plantar pressure in each region was compared separately in Figures 15 and 16. The static test was conducted as follows: the participant maintained a standing position for 30 seconds with their feet positioned shoulder-width apart and their arms aligned alongside their legs

Table 3. The results of the PEDAR system in static mode with and without insoles (WI).

	Shakouri et al. 2020		**Ghassemi et al. 2015**		**Safaeepour et al. 2021**			**PSI**
Prescribed locations	WI (kPa)	SIF (kPa)	WI (kPa)	CTI(P-S-E) (kPa)	WI (kPa)	FSI (kPa)	WI (kPa)	PSI (kPa)
Forefoot	30.3	30	76.8	13.2	27.5	30	34.2	34
Hindfoot	70.2	40	102.2	31.3	52.6	45.3	77.3	52

WI: Without Insoles, SIF: Silicone Medical Insoles with a Universal Fluid Layer, CTI: Flat Silicone Insoles, PSI: Prefabricate Common Silicone Medical Insoles.

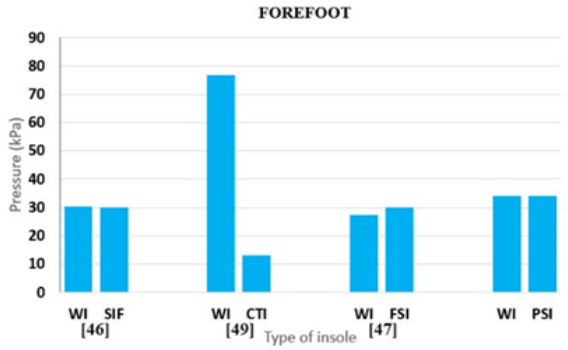

Figure 15. Comparison of pressure in the Forefoot region during stand phase, with and without (WI) medical insoles.

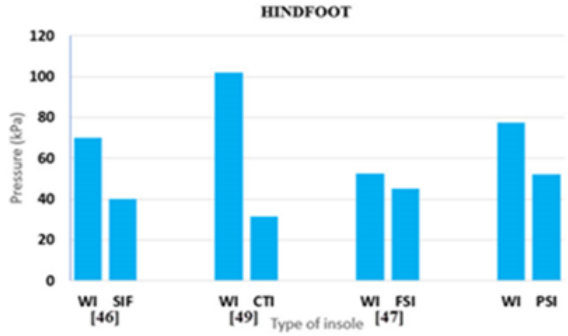

Figure 16. Comparison of pressure in the Hindfoot region during stand phase, with and without (WI) medical insoles.

The findings obtained from the PEDAR system for the stance phase, in conjunction with medical insoles, indicate that SIF, CTI, FSI, and PSI reductions in plantar pressure of 30%, 75%, 6%, and 23%, respectively, compared to the without of utilizing any insoles.

A detailed examination of the results of the stance phase on the forefoot, in conjunction with the use of medical insoles, reveals that SIF, CIF, and PSI resulted in reductions in plantar pressure of 1%, 83%, and 0.7%, respectively, compared to conditions without insoles.

While the use of an FSI is associated with a 9% increase in plantar pressure.

A detailed examination of the results of the stance phase on the hindfoot, in conjunction with the use of medical insoles, reveals that SIF, CTI, FSI, and PSI resulted in reductions in plantar pressure of 43%, 69%, 14%, and 33%, respectively, compared to conditions without insoles.

4. Discussion

In this study, similar to prior research in the field, pressure on the plantar region was measured using two different conditions: with and without the use of medical insole.

Data were collected using the PEDAR system during both stance and gait conditions. In the absence of using medical insoles, the majority of pressure concentrate in the anatomical regions associated with increased risk, including the hallux, the first and second metatarsals, and the heel, and low-risk areas that is, where there is less pressure include the medial midfoot, third to fifth metatarsals, and second to fifth toes. This issue is explicitly referred to in articles (Boulton et al.1987, Nouman et al. 2017, Tsung et al. 2004, Owings et al. 2008, Milford et al. 2016).

In this study, an investigation was conducted to compare the efficacy of four distinct types of medical insoles designed specifically for individuals with diabetes. The evaluation was based on data acquired from the PEDAR system, during both stance and gait conditions. The findings reveal that in terms of pressure reduction during the stance phase, the CTI produced using CNC machining, followed by SIF, exhibited the most substantial decrease in pressure. Insoles constructed from Plastozote-Silicone-EVA foams using CNC machining demonstrated a reduction in plantar pressure of 75% in the stance phase and 54% during gait, relative to conditions without insoles. Additionally, insoles incorporating a fluid layer composed of silicone and silicone gel materials resulted in plantar pressure reductions of 30% and 32%, respectively, in both stance phase and gait conditions, as compared to the no-insole condition. Conversely, the reduction in pressure demonstrated by the flat and prefabricated soles was found to be negligible when compared to the aforementioned two insole designs. In other studies (Tsung et al. 2004, Prasetyanto et al. 2024), similar to the present investigation, it has been demonstrated that designed and customized insoles exhibit superior performance compared to prefabricated insoles. Most importantly, the SIF not only have acceptable pressure reduction but also transfers pressure from high-risk areas, which have high pressure, to low-risk areas, which have lower pressure. For instance, the pressure in the region corresponding to the toes 2-5 is measured 64 kPa without insoles, whereas with the SIF it is measured 189.5 kPa. Similarly, the pressure in the Medial arc foot is recorded 25 kPa without insoles, while with the SIF yields a pressure of 100 kPa.

After analyzing the laboratory data, it is essential to consider several factors regarding the materials and performance of the insoles. The results obtained from the PEDAR system indicate that the CTI manufactured using the CNC method demonstrates superior efficacy in reducing pressure on the plantar compared to the SIF, both during the stance and gait phase. However, it is crucial to note that the thickness of the CTI is approximately 6 mm greater than that of the SIF in the rear and middle regions. This significant difference in thickness implies that the CTI may not be compatible with all types of footwear, necessitating the design or preparation of special shoes to accommodate it.

Foam materials exhibit a decline in effectiveness after repeated use, primarily due to the inherent property of foam that results in a reduction of its initial thickness under the weight of the user. In contrast, silicone materials demonstrate superior reversibility and pressure-damping capabilities, which can be maintained over extended periods.

Custom insoles are specifically designed for each individual to conform to the arch of the foot. Consequently, the process of designing and manufacturing these insoles using a CNC machine is both time-consuming and costly (Paton et al. 2012), resulting in a higher price point compared to the other types of insoles discussed in this research but SIF are manufactured through the molding method. The incorporation of fluid in the intermediate layer eliminates the necessity for individual customization; instead, the insole adapts to the arch of each person's foot upon initial use. This self-customizing characteristic facilitates mass production, significantly reducing manufacturing costs.

Insoles that incorporate a fluid layer generate fluid movement during gait, resulting in a massage effect beneath the feet. This mechanism enhances blood circulation in the plantar region and is particularly beneficial for individuals with diabetes.

In Geffen's study (2007), it was found that prescribing insoles with a low Shore A value (15 degrees) compared to insoles with a higher Shore A value (30 degrees) does not have a significant negative effect on the stability of body posture in patients with diabetic neuropathy. This has been proven in Safaeepour 's (2021) article and low shore has also been used in Shakouri's article (Shakouri et al. 2020).

According to the study conducted by Waaijman and Bus (2012), the evaluation of the interdependence of maximum peak pressure and peak pressure–time integral in the analysis of foot pressure in diabetic neuropathy patients wearing different types of off-load shoes and the results showed that the two parameters are directly correlated in common areas for development of diabetic foot ulcer and there is no need to report both parameters in one Studying is not barefoot, for this reason, the peak pressure–time integral was not reported in this article.

In summary, the analysis of various studies indicates that the use of insoles is essential for individuals with diabetes. However, numerous parameters must be considered when selecting a medical insole.

5. Conclusion

In this study, among the insoles examined, the three-layer Plastozote-Silicone-EVA insole demonstrated a greater decrease in pressure compared to the other insoles. CTI reduction in pressure on the soles of approximately 20% in gait conditions and 40% in the stance phase. However, these insoles present several drawbacks, including limited compatibility with various shoe types, significant thickness, raised cost, reduced durability attributable to the foam material, a decline in initial efficiency over time, and a labor-intensive design and manufacturing process that demands considerable time from the patient. In contrast, the SIF offers both satisfactory pressure decreases and mitigates the disadvantages associated with custom insoles.

In general, it is advisable for all individuals, particularly those with diabetes, to utilize standard medical shoes and insoles. Standard medical insoles have been shown to alleviate pressure on the plantar to an acceptable level. Medical insoles can decrease plantar pressure and redistribute pressure from high-risk areas to lower-risk areas. The use of custom-made insoles provided a more significant and even reduction in peak plantar pressure compared to prefabricated insoles. The findings suggest that there is currently no universally applicable medical insole that can be prescribed for all patients. Therefore, it is advisable to evaluate individual cases and identify a more suitable medical insole tailored to each person's specific needs.

Ethics approval

The research design and protocol were approved by the ethical standards of Research Committee of the Islamic Azad University-North Tehran Branch.

Consent to participate

All the authors voluntarily agree to participate in this research study.

Consent for publication

All authors consent to the publication of the manuscript, should the article be accepted by the Editor-in-chief upon completion of the refereeing process.

Data availability statement

The experimental datasets obtained from this research work and then the analyzed results during the current study are available from the corresponding author on reasonable request.

Disclosure statement

The authors have no known competing interests (financial, personal or other) that could have influenced this work.

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