

Footwear Appropriateness among Diabetic Patients: Findings from a Prospective Podiatric Examination

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Abstract

Compliance with the use of therapeutic footwear (TF) aimed at preventing diabetic foot ulcers remains notably insufficient. The main goal of this research was to assess public awareness of ulcer formation and/or recurrence risks in relation to footwear selection. The secondary objective was to analyze how patients' footwear choices align with their individual risk levels. From 1 September 2017 to 31 August 2018, forty podiatrists took part in the study, completing six-section forms that included demographic data, risk grading, footwear specifications, and a knowledge survey. A total of 1507 patients were enrolled, excluding those with active ulcers. Among them, 43% were classified as risk level 0, 19% as level 1, 19% as level 2, and 19% as level 3. Foot deformities were observed in 58% of participants. Although nearly half of the high-risk patients were aware of their ulceration risk, most failed to comply with recommendations. Only 36% of patients in risk class 3 wore footwear suitable for their risk level. Footwear choice was generally poor, emphasizing the urgent need for better education and adherence to footwear guidelines.

Keywords: Adherence, Therapeutic footwear, Diabetic foot, Podiatrist, Prevention

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Introduction

The International Working Group on the Diabetic Foot (IWGDF) emphasizes that preventing diabetic foot ulcers (DFUs) remains a challenging but crucial objective. Major risk factors include loss of protective sensation (LOPS), peripheral artery disease (PAD), and foot deformities. Moreover, patients with a history of ulceration or lower limb amputation face up to a 40% higher risk of new ulcer formation within one year of healing [1]. Additional elements such as pre-ulcerative lesions, mechanical stress, healthcare costs, quality of life, and adherence levels are essential in DFU prevention. Diabetic individuals without

these risk factors are not at increased risk compared with non-diabetic individuals [2].

Researchers have also drawn attention to the psychological dimension of DFUs. Restricted mobility and the burdens of disease management often trigger depression, frustration, and low self-worth—factors that contribute to poor adherence and preventable complications like amputations [3].

According to IWGDF, five essential pillars underlie ulcer prevention [2]:

- Identification of feet at risk.
- Routine examination and monitoring of at-risk feet.
- Education of patients, families, and healthcare professionals.

- Consistent use of suitable footwear.
 - Ongoing evaluation of ulceration risk factors.
- Furthermore, specific recommendations regarding footwear design and usage are outlined [2]:
- Diabetic individuals should consistently wear accommodative, properly fitted therapeutic footwear.
 - For those with LOPS, barefoot walking, wearing shoes without socks, or thin-soled slippers indoors or outdoors should be avoided.
 - Patients with LOPS must have access to and be encouraged to wear TF throughout the day.
 - Individuals with foot deformities must use TF designed to match their unique shape and fit requirements.

A prospective study indicated significantly lower DFU rates among those using TF compared to controls [4]. Prior investigations have shown that patients with active ulcers generally adhere better to TF use [3–7]; however, poor adherence correlates strongly with re-ulceration [8–10]. Hence, non-removable devices are preferred for acute off-loading phases [11, 12].

Although no universal standard for TF compliance exists [13], objective tracking methods—like step counters, temperature sensors, and activity monitors—are among the most reliable [5, 14, 15]. A major barrier remains the demand for all-day TF wear [12, 16], especially for those recovering from previous ulcers [17, 18]. Many studies further emphasize the necessity of wearing TF both indoors and outdoors [19, 20].

As defined by IWGDF, TF refers to specialized footwear offering therapeutic benefits beyond regular shoes. Its characteristics include proper fitting, customization, accommodative features, reduced plantar pressure, extra depth, adjustable width, rocker soles, smooth linings, secure fastenings, and space for custom orthoses [2]. Thus, any preventive program for foot ulcers must underscore the central role of TF.

This research aimed to address two fundamental questions:

- Do patients possess adequate understanding of preventive footwear principles according to their ulceration risk?
- Are patients actually wearing footwear appropriate for their risk classification?

Materials and Methods

In total, 62 podiatrists affiliated with the Diabetic Foot Study Group of the Italian Diabetes Society (SID) took part in participant recruitment and data recording. Nearly 100 podiatrists were personally contacted by telephone, but only 62 agreed to join the study. Before beginning, all were instructed by the supervising research team (SG) on standardized data collection procedures and were each provided a unique identification number known as “Centre ID.”

Participants eligible for inclusion were adults (≥ 18 years) of either gender diagnosed with diabetes (DPs) who visited a podiatry clinic between 1 September 2017 and 31 August 2018.

Prior to participation, verbal informed consent was obtained. According to local regulations, ethics committee approval was unnecessary due to the study’s observational design. The entire process followed the Helsinki Declaration, ensuring anonymity and data confidentiality. Each podiatrist was supplied with a digital data-entry program, also made available via the SID website at: <https://www.siditalia.it/sid/gruppi/320-podopatia-diabetica#documenti-pubblicazioni>.

Those unable to use the digital tool completed a printed form (Supplementary S1). Instructions on how to conduct the examinations and fill out the forms were also distributed (Supplementary S2).

After collection, the completed data sheets were sent electronically to the SG for central processing.

The data acquisition process consisted of four key phases:

- Gathering demographic information.
- Risk classification for ulceration.
- Documenting footwear features and types (see Supplementary S2 and S3).
- Conducting the patient knowledge survey.

Demographic data

Recorded parameters included gender, age, diabetes duration, and educational background. Information regarding current medications and the referring physician was also noted.

Definition of ulceration risk

Participants were assigned to one of four risk levels according to the IWGDF criteria:

- Class 0: Minimal risk—no signs of LOPS or PAD.
- Class 1: Mild risk—presence of either LOPS or PAD, without foot deformity.
- Class 2: Intermediate risk—combination of LOPS with PAD, or LOPS with deformity, or PAD with deformity.
- Class 3: High risk—presence of LOPS or PAD along with a previous ulcer, minor, or major amputation.

Peripheral artery disease (PAD) was diagnosed through the absence of posterior tibial or dorsalis pedis pulses. If swelling around the ankle or on the dorsum of the foot prevented palpation, the result was labeled as “not assessable.”

Neuropathy was determined by loss of protective sensation (LOPS), using the monofilament test [21]. The procedure took place in a quiet setting, with the monofilament applied perpendicularly to the skin while ensuring the patient could not observe. Testing included three locations per foot: the hallux and bases of the first and fifth metatarsals. Inability to sense two out of three areas indicated LOPS.

Foot deformities were assessed by examining the shape and pressure distribution of the foot, identifying overload areas through the presence of thick plantar calluses.

Finally, any record of previous ulceration, Charcot arthropathy, or partial/complete foot amputation was documented.

Types and characteristics of footwear

The following footwear features were documented:

- Type a – Open footwear: commercially available sandals and similar styles (e.g., flip-flops, open slippers).
- Type b – Closed footwear: standard retail closed shoes such as moccasins, heels, slippers, or boots.
- Type c – Sneakers: mass-produced athletic or casual sports shoes.
- Type d – Therapeutic footwear: either pre-fabricated or custom-made shoes designed to fit individualized orthotic inserts, free of internal seams, featuring a rigid or semi-rigid sole, flexible or self-adjusting upper, extra depth, and a rocker-bottom outsole.

Outsole: categorized as flexible, biomechanical semi-rigid, or rigid.

Upper: could be thermoformable, elastic, adaptive, or rigid.

Incorrect size/fit: evaluated by inserting a finger at the heel area to detect whether the shoe was too long or too short.

Proper width was measured using a tape across the metatarsal region.

Internal seams: assessed manually by feeling the inner surface of the shoe, with particular attention to the forefoot area.

Insole accommodation: noted if the footwear was suitable for orthotic inserts.

Insole type: recorded as custom-made, pre-molded, or standard retail.

After the assessment, podiatrists determined whether the selected footwear matched the patient's ulceration risk level, following IWGDF guidelines. The recommendations specify:

- For risk 1–3 patients without or with minimal deformity, and no pre-ulcerative lesions or ulcer history: shoes that conform well to foot shape and provide proper fit.
- For risk 2 or 3 patients with significant deformities or pre-ulcerative conditions: custom or extra-depth shoes, tailored insoles, or digital orthoses.
- For risk 3 patients with a previously healed plantar ulcer: therapeutic footwear proven to reduce plantar pressure during ambulation, to lower recurrence risk.

Patient questionnaire

Each participant completed a 10-item survey, consisting of nine closed and one open question (Table 1). The survey evaluated knowledge and understanding of preventive care principles and footwear use, divided as follows:

- Four questions on education regarding footwear.
- Four questions on awareness of footwear's preventive role.
- Two questions on adherence behavior.

Table 1. Footwear questionnaire

Question Number	Question
1	Did someone recommend the footwear you're wearing today? ☐ YES ☐ NO If so, who made the recommendation? ☐ Endocrinologist ☐ Podiatrist ☐ Physiatrist ☐ Orthopedic technician ☐ Orthopedic surgeon ☐ Other: _____
2	Do you feel that the footwear you're currently wearing is appropriate? ☐ YES ☐ NO
3	How many hours each day do you use this footwear? _____
4	Do you think footwear can contribute to the development of foot ulcers? ☐ YES ☐ NO
5	Have you been advised that your feet are at risk for (recurrent) ulceration? ☐ YES ☐ NO
6	Do you personally believe your feet are at risk for ulceration? ☐ YES ☐ NO
7	Have you received guidance on selecting suitable footwear? ☐ YES ☐ NO
8	Can you list at least three recommendations you received about footwear? 1 _____ 2 _____ 3 _____
9	Are you able to adhere to the footwear recommendations provided? ☐ YES ☐ NO
10	Do you find the footwear recommendations overly restrictive? ☐ YES ☐ NO

To the authors' knowledge, no validated instrument exists for assessing footwear compliance among diabetic individuals at risk for foot ulceration. Therefore, this survey was developed by a group of clinicians with substantial experience in diabetic foot management, aiming to create a simple, practical tool tailored to the study's objectives. It should be noted that this questionnaire has not been validated, which represents a limitation of the study.

Statistical analyses

Data were analyzed using SAS software (JMP12; SAS Institute, Madison, WI, USA).

Descriptive statistics summarized demographic data, with continuous variables reported as mean $\pm$ standard deviation, and categorical data presented as percentages.

Group differences were tested using the chi-squared test, and p-values < 0.05 were deemed statistically significant.

Results

Data were obtained from 40 podiatric centers during the study. Among these, 61% operated within public hospitals, 29% in private facilities, and 10% collected data across both sectors.

Initially, over 1800 participants were screened; however, poorly completed forms were excluded, leaving 1766 valid datasets.

Demographic data

The study population had a mean age of 71 ± 11.5 years, with 56% males, and an average diabetes duration of 17 ± 11 years. About 52% had low educational attainment, and 48% were insulin-dependent, typically with a longer disease history ($p < 0.0001$) (Table 2).

Table 2. Baseline patient characteristics

Characteristic	Value
Age (mean $\pm$ SD)	71 ± 11.5
Duration of diabetes (years $\pm$ SD)	17 ± 11
Gender (% male)	56
Insulin therapy (% yes)	48
Low education level (%)	52
Charcot foot (% yes)	2
History of ulcer or amputation (% yes)	24
Current ulceration (% yes)	15
Foot deformity (% yes)	58

(Abbreviations: SD = standard deviation; DM = diabetes mellitus)

A total of 60% of the participants were referred by endocrinologists.

Twenty-four percent reported a previous ulcer or minor amputation, and 2% had a history of Charcot neuro-osteoarthropathy, confirmed by medical documentation or self-report.

Approximately 15% had active ulcers at the time of evaluation and were therefore excluded. As a result, the final statistical analysis included 1507 patients.

Foot deformities—such as hammer toes, claw toes, hallux valgus, pes cavus, or flatfoot—were found in 58% of cases.

Deformities were significantly more common among risk class 3 individuals (73%, $p < 0.0001$) compared with other risk categories.

Ulceration risk classification

Based on the IWGDF risk categories, the participants were distributed as follows: 43% in class 0, 19% in class 1, 19% in class 2, and 19% in class 3. As anticipated, the largest proportion of patients belonged to class 0, while classes 1, 2, and 3 showed an almost uniform distribution pattern (Figure 1).

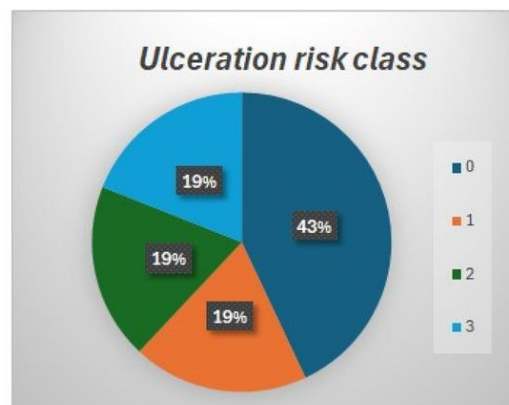


Figure 1. Distribution of patients according to ulceration risk class

Patient questionnaire

Patient responses to the questionnaire were summarized as follows (Figure 2):

- Only 28% of participants reported wearing footwear that had been specifically recommended, mostly by endocrinologists (13%) or podiatrists (9%).
- Ninety percent (90%) believed their shoes were appropriate.
- Average daily use of footwear was 8 ± 3.9 hours.
- 57% of participants thought footwear could be a cause of foot ulcers.
- 51% had received some form of information about the risk of ulceration or re-ulceration.
- 37% recognized that their own feet were at risk.
- 45% said they knew what type of footwear they should wear.
- The most common advice referred to therapeutic footwear (TF) — with flexible uppers, no internal seams, and allowance for insoles.
- 43% stated they could follow the recommended footwear guidance.
- 91% of respondents felt that the recommendations were reasonable and not excessive.

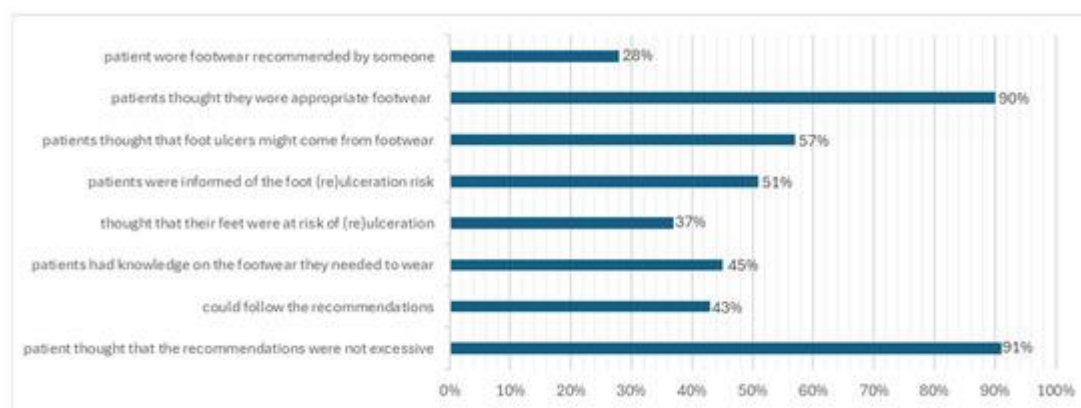


Figure 2. Patient responses to the footwear questionnaire

Overall, 37% of all patients were aware of their ulceration risk, and among these, the majority wearing TF (62%) were those in risk class 3.

Footwear types and features

Survey findings revealed that 45% of patients used standard closed footwear, 25% wore sneakers, and 17% used open footwear. Only 13% were observed wearing therapeutic footwear (TF) (Figures 3 and 4).



Figure 3. Distribution of footwear types among participants

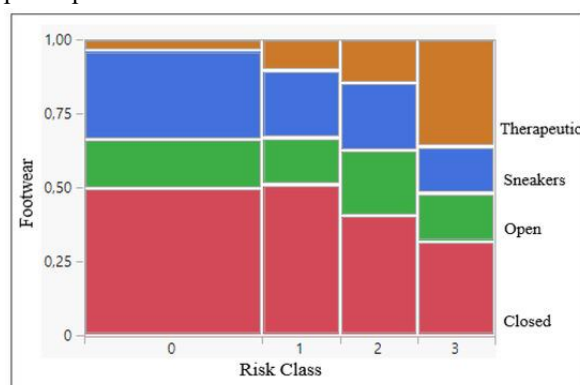


Figure 4. Cross-analysis of footwear type by risk class ($p < 0.0001$)

According to Table 3, patients in risk class 3 demonstrated a notably higher use of TF compared with other risk categories ($p < 0.0001$).

Table 3. Percentage of footwear types by ulceration risk class

Risk Category	Closed Footwear (%)	Open Footwear (%)	Sneakers (%)	Therapeutic Footwear (%)
0	45.5	17	30	3.5
1	51	16	23	10
2	41	22	22.5	14.5
3	32	16	16	36

0	45.5	17	30	3.5
1	51	16	23	10
2	41	22	22.5	14.5
3	32	16	16	36

- Outsole: Within risk class 3, 35% of participants wore shoes with rigid soles, significantly more than in other classes, where flexible soles were predominant ($p < 0.0001$).
- Upper: Class 3 footwear showed a greater frequency of thermoformable, elastic, or self-adapting uppers, with fewer rigid uppers than lower risk classes ($p < 0.0001$).
- Incorrect size or fit: About 12% of participants wore footwear with improper sizing or fit, including 7% in risk class 3.
- High-heeled shoes: 6% of the total sample wore shoes with heels higher than 4 cm, including 5% among class 3 patients.
- Internal seams: 36% of all shoes had internal stitching, but this dropped to 17% in risk class 3.
- Designed for insoles: Overall, 44% of shoes were suitable for orthotic inserts, whereas 29% of class 3 patients' shoes lacked this feature.

Discussion

Our findings indicated that 57% of participants recognized a connection between improper footwear and foot ulcer formation, while 51% had received guidance regarding ulceration or re-ulceration risks. This level of awareness about the consistent use of therapeutic footwear (TF) is essential, since Alkhatieb MT *et al.* [22] recently demonstrated in a cross-sectional study that the recurrence rate of diabetic foot ulcers (DFU) was significantly lower among TF users compared with non-users (27.8% vs. 52.5%).

Although 90% of participants believed that their footwear was suitable for their ulceration risk level, only 36% of those in risk class 3 actually wore TF. This highlights a major misperception about what constitutes proper footwear. Moreover, over half of the patients lacked

accurate knowledge of the footwear they should be wearing — a concerning statistic given that 25% had a moderate-to-high risk of ulceration. These data imply that patients have not been adequately informed about their foot health. This may stem either from low patient engagement in foot self-care or from limited emphasis on TF among healthcare providers. In fact, as noted by [23], diabetic patients frequently receive insufficient foot-care attention from their care teams. Evidence shows that a combined approach involving trained medical staff, patient education, preventive measures, TF, and routine monitoring can lower amputation rates by 49–85% [24]. A core focus of our study was the patient's perception of foot risk. While TF is not primarily intended to accelerate healing, it is vital for preventing both initial and recurrent ulcerations [25]. Only 37% of all respondents believed that their feet were at risk, yet within risk class 3, 62% reported using TF. This suggests that patients at higher risk tend to be more aware and more compliant with clinical recommendations. Alkhatieb MT [22] similarly reported that 47% of high-risk patients wore TF and 46% adhered to its use. According to Knowles and Boulton [6], diabetic patients must be made aware of the severity of their foot conditions and the protective value of TF. In our research, nearly half of the patients had received proper footwear advice; however, 57% still failed to adhere to the recommendations, even though most considered the guidance reasonable and not excessive.

Adherence to TF is likely to improve only when two key factors are present: an understanding of the foot condition as a genuine problem, and recognition of the footwear's benefits. TF has often been described as a “visible manifestation of the disease”, symbolizing the patient's diabetic foot condition [26]. Supporting this, López-Moral M *et al.* [27] reported in a prospective multicenter trial that greater adherence to TF significantly reduced ulcer occurrence, reinforcing the importance of patient education [25].

In our data, risk class 3 patients used TF for an average of 8.6 hours per day, approximately 70% of their waking time. Jar G *et al.* [5] reported a median wearing duration of 8–12 hours daily. Robust clinical evidence confirms that consistent TF use prevents the recurrence of plantar ulcers, particularly under the metatarsal heads [17, 28], as it can reduce plantar peak pressure by about 50% when worn for more than 60% of the day [29].

The optimal therapeutic outcome in diabetic foot management depends on the combination of proper pressure relief and consistent footwear use [28]. However, nonadherence significantly reduces the effectiveness of preventive strategies [30]. Our findings support this, revealing that while 70% of individuals in risk class 3 reported wearing specialist-recommended footwear, only 36% actually wore appropriate shoes. Similarly, Sudha B.

G [13], in a cross-sectional analysis using a 10-item survey similar to ours, found that only 30.5% of participants had received foot-care training, and just 12% demonstrated strong retention of that knowledge. The study also cited several barriers to effective diabetic foot care — including low financial support, travel burdens, family dependency, religious customs promoting barefoot walking, and communication gaps between patients and clinicians.

Diabetic individuals should wear properly fitting shoes that both protect and conform to the natural foot shape, offering sufficient length, width, and depth for comfort and safety [31]. Still, numerous studies show that many diabetic patients wear ill-fitting footwear [32]. In our dataset, only 17% of those in risk class 3 wore shoes with internal seams, and 7% wore shoes of the wrong size or fit. Moreover, these patients tended to prefer flexible, elastic, or self-molding uppers and exhibited a notably higher use of rigid out-soles than other classes. López-Moral M. *et al.* [27] reported that high-risk patients using rigid rocker soles faced a 64% lower chance of ulcer recurrence compared with those using semi-rigid soles, underscoring how poorly designed footwear can trigger ulcers by increasing pressure, shear stress, and friction [19].

Therapeutic footwear (TF) has proven superior to standard footwear in reducing forefoot peak pressure among diabetic patients [33]. Yet, our observations showed that only 36% of risk class 3 participants wore TF. Uccioli *et al.* [34] demonstrated a marked reduction in ulcer incidence among high-risk patients who used custom therapeutic shoes and insoles compared with those choosing their own shoes (58.3% vs. 27.7%). Notably, orthotic inserts play a role as crucial as the footwear itself [35]. In our study, nearly all patients in risk class 3 who wore TF also used custom-made orthotics, indicating that TF prescriptions for high-risk patients are typically accompanied by personalized orthotic devices.

To improve adherence, some researchers have suggested creating “intelligent footwear” that looks like regular shoes but includes a removable pressure-sensing system capable of identifying high-pressure zones and automatically reshaping the insole. Although promising, these technologies require further clinical validation [22]. Moreover, adherence to foot care is often hindered by depression, a common comorbidity in diabetes. Therefore, routine screening and management of depression are strongly recommended [10, 36]. Emerging technologies — such as AI-assisted monitoring tools (e.g., smart socks and insoles) — have shown potential in improving ulcer prevention and patient compliance [3]. Other innovations that may support long-term adherence include infrared thermography, plantar pressure analysis, mobile foot-care units, telemonitoring, and rehabilitation centers, particularly beneficial for rural populations [13].

Patients' awareness, aesthetic preferences, and personal beliefs also influence compliance with therapeutic footwear [25]. As such, clinicians must continually reinforce educational messages to support sustained behavioral change [37].

Research on interventions aimed at improving TF compliance remains limited [28]. However, Keukenkamp R. *et al.* [38] demonstrated that motivational interventions (MIs) can have short-term positive effects. Given their central role in diabetic foot care, podiatrists are ideally positioned to motivate patients and promote better self-care habits. They should also take the lead in implementing short- and long-term educational programs to enhance compliance and understanding [39].

Conclusions

There remains a significant deficit in knowledge and awareness regarding the necessity and benefits of therapeutic footwear for preventing foot ulceration. Even when explicitly prescribed, many patients fail to follow clinicians' recommendations.

Just over one-third of patients in the high-risk category wear suitable footwear for their foot condition. Overall, compliance and awareness remain low.

We recommend that healthcare providers strengthen patient education, monitor compliance, and implement ongoing educational initiatives to improve adherence to prescribed therapeutic footwear.

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