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# Proper Foot Orthoses Type to Prevent Foot Ulcers in Patients with Diabetes: A Systematic Review

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## ABSTRACT

**Introduction:** One form of diabetic polyneuropathy is the presence of ulcers in the limbs, where the most common location for ulcers is the plantar area. Various orthoses are prescribed for diabetic patients, but no results have been obtained on which orthoses are effective in these preventive efforts. This review aims to provide a general review of the efficacy of various foot orthoses for preventing foot ulcers in diabetic patients.

**Methods:** The following databases were used for a computerized literature search up to October 2022: PubMed, ScienceDirect, and Google Scholar. The modified Jadad score is used to assess the quality of this study. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines were followed while conducting this systematic review.

**Results:** In all, six papers met our inclusion criteria, with 2 receiving a low study quality rating and 4 a good rating. All the studies revealed a considerable use of the insole as an orthosis to prevent foot ulcers in diabetic patients. Some studies also mention plantar pressure to determine the effect of orthoses. The other evaluation is also about QoL and adherence, and it mentions ulcer recurrence within several months.

**Conclusion:** Foot orthoses can help prevent foot ulcers in diabetic patients, but due to the limited information (as all studies focus only on insoles and shoes), future studies should investigate other types of orthoses and their effects.

***Keywords:*** diabetic foot, foot orthoses, foot ulcer

## INTRODUCTION

Diabetes mellitus (DM) frequently results in diabetic peripheral neuropathy (DPN), a condition characterized by the presence of symptoms and signs of peripheral nerve dysfunction in individuals with diabetes, after the exclusion of other causes.[1] DPN is a significant risk factor for diabetic foot ulceration, a precursor to lower-extremity amputation that can have profound physical and psychological impacts on patients.[2,3] Preventing and managing diabetic foot ulcers remains a critical challenge, and clinical strategies have evolved over time to address this issue, including the use of casting, therapeutic footwear, surgical interventions, and offloading techniques.[4]

Among these interventions, the use of appropriate footwear to reduce plantar pressure is commonly employed in patients at high risk for foot ulceration.[3] Properly fitting footwear plays an essential role by providing physical protection, acting as an environmental barrier, offering biomechanical support, and redistributing pressure across the foot, thereby reducing

callus formation and preventing ulceration.[5] In contrast, poorly fitting footwear—whether too tight or too loose—can exacerbate plantar pressures, increase friction, and contribute to the formation of foot ulcers,[6,7] which can lead to infections and, ultimately, amputation.[7] This issue is particularly concerning for individuals with DPN, who are vulnerable to increased tissue stress due to significant loss of sensation in the feet.[8]

The characteristics of appropriate footwear for individuals with DPN are well-defined. Footwear should be sufficiently wide around the heel, made of leather, free from internal seams, and include a semi-rigid heel counter. Additionally, it should feature a wide anatomical sole, adjustable lacing or Velcro, and a heel height of 2-3 cm to provide adequate cushioning, volume, and width tailored to the individual's foot size. Furthermore, proper fitting should occur while the patient is weight-bearing to ensure the shoe's effectiveness.[9]

Given the critical role that proper footwear plays in preventing foot ulceration in individuals with DPN, this study aims to evaluate whether patients with DPN use footwear that meets these recommended criteria. The inability to perceive increased pressure in the feet makes individuals with DPN particularly susceptible to developing foot ulcers, making the selection of appropriate footwear essential in minimizing ulcer formation and subsequent complications.

## METHODS

### Search Strategy

A systematic search was conducted to identify relevant studies assessing the efficacy of various foot orthoses for preventing foot ulcers in diabetic patients. The search was conducted in PubMed, ScienceDirect, and Google Scholar, with inclusion of studies published up to October 2022. Search terms included combinations of keywords such as "diabetic foot ulcers," "diabetic neuropathy," "foot orthoses," "insoles," "footwear," and "plantar pressure," ensuring comprehensive coverage of all relevant literature.

### Inclusion and Exclusion Criteria

The inclusion criteria for this review were studies involving patients with diabetic type 1 or type 2 diabetes. The studies needed to focus on the use of foot orthoses, such as insoles or shoes, for preventing foot ulcers in diabetic patients. Furthermore, only studies that reported data on plantar pressure, quality of life (QoL), adherence, and ulcer recurrence were included. Randomized controlled trials (RCTs) and observational studies with a clear description of the outcomes of interest were also considered. Studies that focused on patients with active foot ulcers at the time of the study or did not address the use of foot orthoses for ulcer prevention were excluded from the review. Additionally, non-peer-reviewed articles, abstracts, and studies with incomplete data were excluded from the analysis.

### Outcome of Interest

The primary outcome of interest was the efficacy of foot orthoses (insoles, shoes) in preventing diabetic foot ulcers. Secondary outcomes included reductions in plantar pressure, improvements in quality of life (QoL), patient adherence to the orthosis regimen, and the recurrence of foot ulcers within a specified follow-up period.

### Quality Assessment

The methodological quality of each study was independently assessed using the modified Jadad score, which evaluates clinical trials based on randomization, blinding, and the reporting of withdrawals and dropouts. A score of 0-3 was classified as low quality, and a score of 4-7 was classified as good quality. This assessment was crucial in determining the robustness of the included studies and their relevance to the research question.

**Data Extraction and Analysis**

Each trial was identified by the search method mentioned above and assigned to the topics. A self-designed data extraction form was used to independently extract content by researchers, including the lead author, year of publication, plantar pressure measurements, intervention group, control group, and outcome measures or results. One reviewer conducted the literature screening, quality evaluation, and data extraction.

**Data Synthesis**

A narrative synthesis was performed due to the heterogeneity of the included studies. The findings were summarized regarding the effectiveness of foot orthoses (insoles and shoes) in preventing foot ulcers, reducing plantar pressure, and improving quality of life and adherence. Studies were also analyzed to assess foot ulcer recurrence rates.

## RESULT

**Study Selection**

The electronic search across three databases—Google Scholar (829 studies), PubMed (148 studies), and ScienceDirect (20 studies)—yielded a total of 977 items. After screening titles, abstracts, and full texts, 42 studies met the initial inclusion criteria. Studies using case studies/series, literature reviews, and qualitative methods were excluded, leaving 6 studies for this systematic review. The flowchart for study selection and exclusion is depicted in Figure 1.

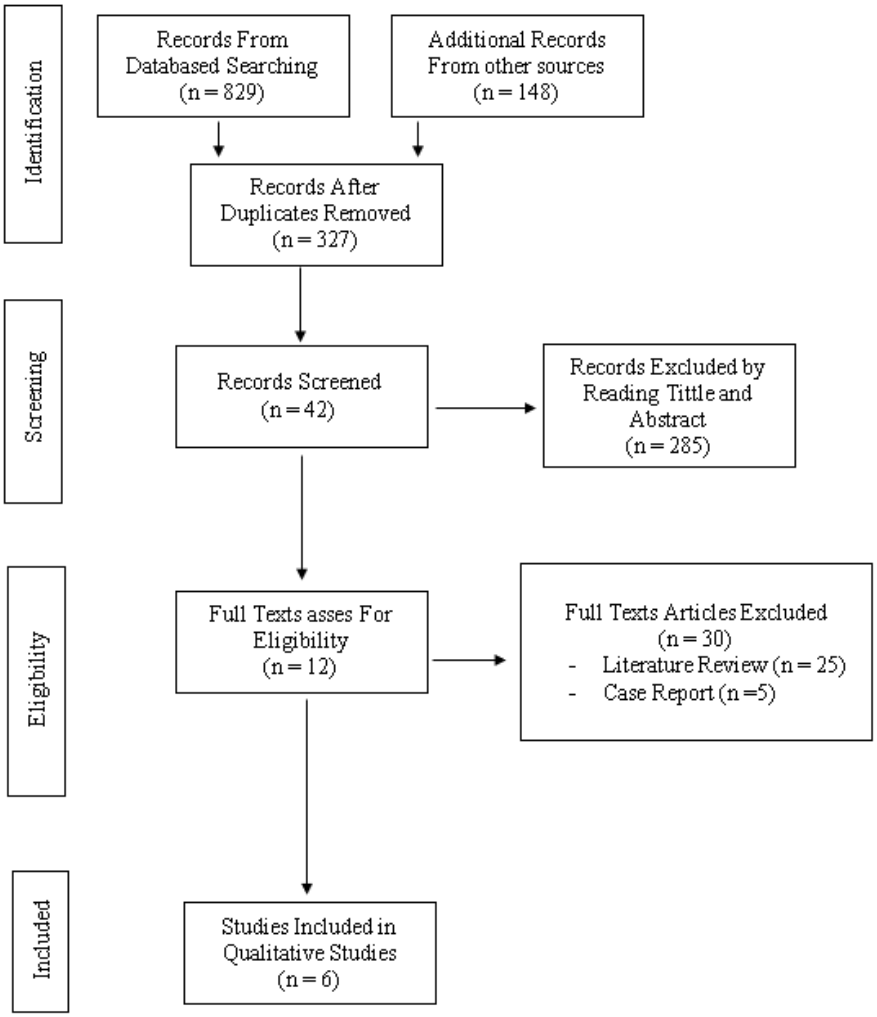


**Figure 1. PRISMA Flow Diagram.**

## Study Characteristics

As summarized in Table 1, all included studies measured plantar pressure. In addition to plantar pressure, the studies also assessed secondary outcomes, including adherence to orthoses, quality of life (QoL), functional status of the lower limbs, patient satisfaction, and the recurrence rate of foot ulcers. There was considerable variation in study methodologies, particularly in the timing of evaluations. Three of the six studies performed pre- and post-evaluations on the same day to assess the immediate effects of orthoses. [10-12] While the remaining three studies assessed the outcomes over longer periods: 10 weeks [13], 12 months [14], and 18 months [15].

All studies used lower-limb orthoses, primarily insoles, to reduce plantar pressure during daily activities. Two studies compared the effects of custom-made shoes and sports shoes in addition to the insoles. Furthermore, several studies compared different types of insoles, such as customized or standard models, to evaluate their respective effects on plantar pressure reduction and other outcomes.

**Table 1. Characteristics of Included Studies on the Efficacy of Foot Orthoses in Preventing Foot Ulcers in Diabetic Patients**

| Author, Year (Location) | Measurement | Time | Type of Orthoses | Outcome / Results |
|---|---|---|---|---|
| Kim, et al., 2018[2] (Korea) | Peak Plantar Pressure | Current time | Control Group: - Experimental Group: Diabetic Socks and Protective Socks + Functional Insoles. | The protective sock with functional insoles significantly reduced peak plantar pressure on the lateral rearfoot but significantly increased it on the middle forefoot and medial midfoot ($p < 0.05$). However, there were no significant differences in the medial and lateral forefoot, lateral midfoot, and medial rearfoot between the diabetic sock and protective sock conditions ($p > 0.05$). |
| Chatzistergos, et al., 2020[6] (United Kingdom) | Plantar Pressure in the entire foot region | Current time | Control group: barefoot Experimental group: Patient-Specific Optimum Insole | The use of the patient-specific optimal stiffness reduced, on average, peak pressure by 46% (±14 %). A statistically significant difference (paired samples *t*-test, $t(13) = -3.733$, $p = 0.003$, $d = 0.997$). |
| Botelho, et al., 2022[9] (Portugal) | QoL, Michigan Neuropathy Screening Instrument (MNSI), Lower Extremity Functional Scale (LEFS), Center of Pressure Test | Current time | Control Group: shoes Experimental group: custom-made insole. | Both groups had no significant differences in QoL before and after the intervention. The experimental group showed significant differences in functional performance on the tests. |
| Abbot, et al., 2019[11] (United Kingdom) | Plantar foot Ulcers occurrence after 18 months | 18 months | Control Group: Insole Experimental Group: Insole + Audiovisual Alert. | The incidence of foot ulceration in the experimental group was reduced by about 71% compared with the control group. |
| Zwaferink, et al., 2020[14] (United States of America) | Plantar Pressure, Patient's Satisfaction | 10 weeks | Control Group: - Experimental Group: Custom-made shoes + Insole, Insole Type A, Type B, and Type C | All data-driven footwear conditions significantly reduced peak metatarsal head pressure compared with non-therapeutic shoes. Custom-made shoes and Insole type A showed the lowest metatarsal head peak pressure → 90-98% of cases were <200kPa. Patients' satisfaction did not differ |

| | | | | |
|---|---|---|---|---|
| | | | | significantly between groups. |
| Keukenkamp, et al., 2021[15] (Netherland) | Adherence, Peak-Plantar Pressure, and Recurrence of Ulcer | 12 months | Insole | Increasing adherence in both groups. Peak Plantar Pressure (More than 200kPa) is less frequent in the Indoor Footwear group. Eight of 31 participants have recurrences of foot ulcers at various locations. |

**Study Quality**

The methodological quality of all included studies was assessed using the modified Jadad score. As detailed in Table 2, all six studies scored 4 or higher, indicating good quality. However, two studies received scores below 4, suggesting they could benefit from improved methodological rigor. The detailed breakdown of the quality assessment for each study is provided in Table 2.

**Table 2. Methodological Quality Assessment Using Modified Jadad Score**

| Author | Question | | | | | | | | Total Score | Quality of Study |
|---|---|---|---|---|---|---|---|---|---|---|
| | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | | |
| Kim, et al. [2] | 1 | 1 | 0.5 | 1 | 1 | 1 | 0 | 1 | 6.5 | Good |
| Chatzistergos, et al. [6] | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 2 | Low |
| Botelho, et al. [9] | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 7 | Good |
| Abbot, et al. [11] | 1 | 1 | 0.5 | 1 | 1 | 1 | 1 | 1 | 7.5 | Good |
| Zwaferink, et al. [14] | 1 | 1 | 0.5 | 1 | 0 | 1 | 1 | 1 | 6.5 | Good |
| Keukenkamp, et al. [15] | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 3 | Low |

Questions:

(1) The study is described as randomized.

(2) The method of randomization is appropriate.

(3) The study was described as blinding (double-blind got one score, single-blind got 0.5 score).

(4) The method of blinding is appropriate.

(5) There is a description of withdrawals and dropouts.

(6) There is a description of the inclusion/exclusion criteria.

(7) The method used to assess adverse effects is described.

(8) The methods of statistical analysis are described.

A total score < 4 is considered a low-quality study. Scores of 4 or more are classified as good quality.

**Foot Orthoses Used to Prevent Foot Ulcers in Diabetic Patients**

The primary focus of this review was to evaluate the effectiveness of foot orthoses (primarily insoles) in preventing foot ulcers in patients with diabetes. Besides that, the participant may not have a foot deformity, which could introduce bias into the results.[4]

Before placing an orthosis, plantar pressure should be measured to assess its effect. Of the six studies, only three explicitly measured plantar pressure before the orthosis was applied. [10,11,15] The remaining studies did not clearly report pre-orthosis plantar pressure measurements. [12-14] The results suggest that foot orthoses, particularly insoles, can significantly reduce plantar pressure, a key factor in preventing foot ulcers. Additionally, some studies reported improvements in adherence to orthosis use and quality of life (QoL), as well as a reduction in foot ulcer recurrence over follow-up periods ranging from 10 weeks to 18 months.

## DISCUSSION

The recurrence of foot ulcers remains a significant challenge for individuals with diabetes.[2,3] Recent randomized controlled trials (RCTs) investigating the efficacy of therapeutic footwear have provided

important insights into principles that should guide footwear prescription for patients with a history of foot ulcers. One study demonstrated that prescribing custom-made footwear resulted in fewer ulcerations compared to not providing footwear at al.[15] While this outcome may seem intuitive to most clinicians, it underscores the importance of evidence-based support for such basic principles of diabetic foot care.

However, another RCT found that a clinician-designed custom insole did not reduce plantar pressure more effectively than an off-the-shelf insole.[12] While the findings may limit generalizability, this study highlights an important message: the mere provision of a "custom-made insole" does not automatically guarantee an improvement in the foot's mechanical environment. This emphasizes the need for more nuanced approaches to orthotic design, beyond just customization.

Furthermore, two studies have shown that directly measuring plantar pressure under the foot, rather than relying solely on foot shape and clinical judgment, can significantly enhance the efficacy of the resulting footwear.[10,11,14] One such study used an algorithm based on foot shape and barefoot plantar pressure to design orthotics, resulting in improved outcomes.[13] This approach reinforces the idea that precise, evidence-driven design methods can improve the effectiveness of foot orthoses in preventing ulcer recurrence.

Another critical factor that emerged from the literature is the importance of patient adherence to wearing therapeutic footwear. A study concluded that footwear is only effective if patients wear it consistently throughout the day.[14] This finding, although perhaps self-evident, has significant implications for both clinical practice and research, highlighting the need to not only focus on the design of orthoses but also to ensure patient compliance.

The contrasting results observed between more recent and older studies on the effectiveness of footwear in preventing ulcer recurrence may stem from several factors. The diversity of interventions and control conditions in these studies, along with the lack of attention to unloading efficacy in some earlier research,[1,4] complicates comparisons. Not all studies measured plantar pressure or unloading before prescribing footwear, which may explain some of the discrepancies in outcomes. However, recent advancements in standardizing protocols and procedures have significantly improved our understanding of the effectiveness of therapeutic footwear in preventing ulcer recurrence in diabetic patients.[4] These developments have provided a stronger evidence base to guide clinical practice and research in this area.

Despite the valuable insights provided by the studies included in this review, several limitations must be acknowledged. First, the heterogeneity of the interventions (e.g., different types of foot orthoses, footwear designs, and study durations) complicates direct comparisons between studies. This diversity in methodologies and outcomes can limit the ability to draw definitive conclusions on the most effective interventions for preventing foot ulcer recurrence. Additionally, the relatively small sample sizes in some studies reduce the generalizability of the results. Most studies have focused primarily on insoles and custom-made shoes, leaving the effectiveness of other types of orthoses, such as braces or offloading devices, underexplored. Furthermore, the lack of consistent plantar pressure measurements prior to the intervention in several studies introduces uncertainty in assessing the orthoses' actual efficacy.

Future research should aim to standardize the methodologies used to evaluate foot orthoses, particularly with regard to pre- and post-intervention plantar pressure measurements. Additionally, larger, multicenter RCTs with diverse populations would provide more robust evidence to guide clinical recommendations. Studies should also explore the impact of a wider range of orthoses on foot ulcer prevention, including braces, splints, and offloading

devices, to better understand their comparative effectiveness. Long-term follow-up studies are needed to determine the sustainability of the benefits of these orthoses over time. Finally, further investigation into patient adherence to footwear use is essential, as consistent use is critical for the effectiveness of these interventions.

## CONCLUSION

This systematic review demonstrates that the evidence supporting footwear and offloading interventions for diabetic foot ulcers has significantly improved in recent years, though gaps remain in certain areas. The strongest evidence suggests that non-removable devices, such as walkers, are effective in healing neuropathic plantar forefoot ulcers. Furthermore, high-quality studies confirm that therapeutic footwear, when worn consistently, is effective in reducing plantar pressure and preventing the recurrence of plantar foot ulcers. However, further research is needed to explore additional types of orthoses and their long-term effectiveness in preventing ulcer formation.

### *Declaration by Authors*

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