

# Evaluation of the Preventive Effect of dw Orthopedic Footwear for Diabetics on Ulcer Relapses in Diabetic Polyneuropathy Patients

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## Introduction

Foot ulcers are a major complication of diabetes mellitus, associated with high morbidity, mortality, and use of public resources.<sup>1-3</sup> A severe complication affecting 6.4% of diabetic patients, leading to amputations and increased mortality.<sup>1</sup> The 5-year risk of death in patients with DFUs is 2.5 times higher than in patients without foot ulcers.<sup>2</sup> Diabetic foot ulcers are the primary cause of approximately 85% of amputations in non-traumatic patients. Patients with DFUs suffer from physical, psychological, and economic trauma caused by this debilitating condition. Treating foot ulcers is challenging due to their multifactorial etiology, and it represents a significant burden on patients, healthcare systems, and society.<sup>4</sup> Even when an ulcer is successfully healed, the risk of recurrence is high, with a 40% recurrence rate in the first year after healing and 65% within the first 3 years.<sup>5</sup> Preventing DFUs is essential to reduce patient risk and the resulting economic burden on society. Clinical evidence of the preventive effect of diabetic footwear is the assessment of the occurrence of reulcerations during the period of wearing such footwear.

## Objective

Evaluate the effectiveness of diawin orthopedic footwear in preventing ulcers and relapses in diabetic polyneuropathy patients.

## Diawin orthopedic shoes

In the study, preventive orthopedic footwear from the Diawin brand, specially designed for the needs of diabetics, was used. This footwear is clinically tested and certified for its biomechanical and physical properties. It is classified as a Class I medical device and is covered by public health insurance in Slovakia and the Czech Republic. Diawin footwear is recommended by the Slovak Diabetes Society and has also received the prestigious certification from the American Podiatric Medical Association (APMA).



3

3 widths for each size



Extra Lightweight



Breathable material: Prevents bacterial growth and maintains an optimal microclimate.



Extra internal volume



Seamless upper: no seams at friction points.



Extra Cushioning



Semi-rigid Rocker Sole - biomechanical outsole.



Rounded Toe Box



Designed for the insertion of a ready-made or custom insole.



Design - Adherence!

## 3 Widths of the prophylactic Diabetic Footwear diawin used in the Study



## Methods

Study design: Retrospective, multicenter, observational study.

Patients: 116 participants with diabetic polyneuropathy and history of ulceration, divided into two groups.



## Results

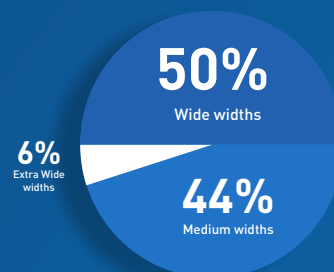
From a statistical perspective, the monitored parameters are balanced between the two groups.

	Experimental group	Control group	p - value
Number of patients (n)	82	34	
Gender (f/m)	42/40 (51.22% / 47.78%)	13/21 (38.34% / 61.76%)	0.2024
Average age	64.65 [SD: 10.13]	64.15 [SD: 10.38]	0.8109 (t-test) 0.9564 (KW test)
Average BMI	32.71 [SD: 6.42]	30.17 [SD: 5.17]	0.0429 (t-test) 0.0707 (KW test)
Diabetes duration in years (average)	15.73 [SD: 9.30]	12.47 [SD: 8.98]	0.0853 (t-test) 0.0538 (KW test)
Insulin therapy	69.51%	61.75%	0.4184
Peripheral arterial disease of legs - PAD	61.54%	64.71%	0.7502
Pedicure treatment	32.93%	26.47%	0.4939
Relaps of ucleration (number of patients)	11 (13.41%)	21 (61.76%)	0.00001

diawin

## Widths distribution of the Diabetic Footwear diawin used in the Study (n=82)

More than half (56%) of patients in the study needed shoes for diabetics in Wide and Extra Wide sizes.



## Localization of ulcers

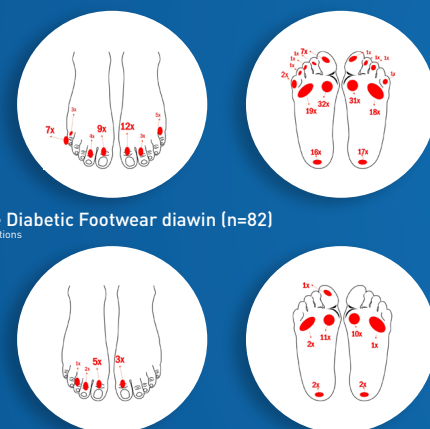
Primarily on metatarsal heads, followed by dorsal toe surfaces and heels.



## Reduction in ulcers

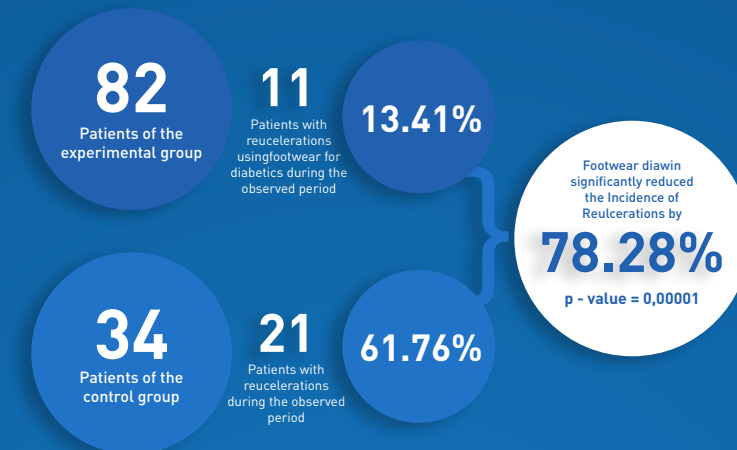
Significant reduction in metatarsal, toe, and heel ulcers after wearing diawin footwear.

Ucleration Localization of patient's feet before the use of Diabetic Footwear diawin (n=82)  
in 82 patients - a total of 183 ulcerations



## Ulcer relapses

The preventive effect of Diawin footwear was achieved in high-risk patients with polyneuropathy and a history of ulceration, who are at high risk of reulceration.



## Conclusions

Diawin footwear reduces the risk of ulcer relapse by 78.28%, proving its effectiveness as a preventive strategy for high-risk patients. Recommendation: Incorporating specialized footwear in diabetes care reduces complications, improves quality of life, and lowers healthcare costs.

## The clinical study was presented at congresses



### Literature

- Zhang Y. et al. (2020)
- Jupiter DC. et al. (2016)
- Petrakis I. et al. (2017)
- Crawford F. et al (2015)
- Armstrong DG. et al. (2017)

Ethical Approval: The entire procedure for this study was approved by the ethical committee of NEDU n.o. Lúbochňa, registration number – "IRB00006715"