

**Electrical Stimulation for Diabetic Foot Ulcers:
A Systematic Review and Meta-analysis of
Randomized Controlled Trials**

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ADMINISTRATIVE INFORMATION**Support** - Youth Science and Technology Project of Health Commission of Hebei Province: Research on the standardization level of self-management of patients with diabetes foot and related factors affecting wound healing (No. 20190002).**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202680089**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 August 2026 and was last updated on 25 August 2026.**INTRODUCTION**

Review question / Objective To systematically evaluate the clinical efficacy of electrical stimulation in the treatment of diabetic foot ulcers.

Condition being studied Diabetic foot ulcer (DFU) is one of the most severe and healthcare resource-consuming chronic complications of diabetes. The refractory nature of DFU results from multifactorial pathophysiological mechanisms. In this context, electrical stimulation (ES) has attracted attention because of its clear biological basis and clinical convenience.

METHODS

Participant or population Eligible studies included patients aged ≥ 18 years with a clear diagnosis of diabetes and foot ulceration. The ulcer grade, severity, duration, and etiological type

(neuropathic, ischemic, or neuroischemic) were not restricted, nor were sex, race, or treatment setting (inpatient or outpatient).

Intervention Regarding participants, eligible studies included patients aged ≥ 18 years with a clear diagnosis of diabetes and foot ulceration.

Comparator Regarding comparators, the control group had to receive standard wound care, sham electrical stimulation (placebo electrical stimulation), or no electrical stimulation.

Study designs to be included Regarding study design, only peer-reviewed parallel RCTs were included, with no restrictions on blinding type.

Eligibility criteria The inclusion criteria for this study were predefined according to the PICOS principle. Regarding study design, only peer-reviewed parallel RCTs were included, with no restrictions on blinding type. Regarding

participants, eligible studies included patients aged ≥ 18 years with a clear diagnosis of diabetes and foot ulceration. The ulcer grade, severity, duration, and etiological type (neuropathic, ischemic, or neuroischemic) were not restricted, nor were sex, race, or treatment setting (inpatient or outpatient). Regarding interventions, the experimental group had to receive any form of electrical stimulation therapy, either as a standalone treatment or as an adjunct to standard wound care. Regarding comparators, the control group had to receive standard wound care, sham electrical stimulation (placebo electrical stimulation), or no electrical stimulation. Regarding outcomes, included studies had to report at least one of the following outcomes: ulcer healing rate (primary outcome, defined as percentage change in ulcer area), and complete healing (secondary outcome, defined as 100% re-epithelialization of the wound surface with no drainage). No restrictions were placed on publication language or year.

Information sources PubMed, Web of Science, the Cochrane Library, and Embase were systematically searched.

Main outcome(s) Ulcer Healing Rate and the number of healed ulcers.

Quality assessment / Risk of bias analysis For randomized controlled trials (RCTs), the Cochrane Risk of Bias 2.0 tool (RoB 2) was used for assessment(27). This tool evaluates risk of bias across five specific domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. Based on the answers to the signaling questions, each domain and the overall study were judged as having "low risk," "some concerns," or "high risk" of bias. The overall risk of bias for each study was determined as follows: 'low risk of bias' if all domains were judged to be at low risk; 'some concerns' if at least one domain was judged to raise some concerns but no domain was at high risk; and 'high risk of bias' if one or more domains were deemed to be at high risk.

Strategy of data synthesis All statistical analyses were performed using Stata version 16.0 software (StataCorp, College Station, TX, USA). Quantitative data from the 10 included studies were synthesized. For the outcome complete healing, risk ratio (RR) was used as the effect measure, and the corresponding 95% confidence interval (CI) was calculated. For the outcome ulcer healing rate,

weighted mean difference (WMD) was used as the effect measure, and the corresponding 95% CI was calculated.

Subgroup analysis To explore the source of heterogeneity, subgroup analyses were further conducted according to ulcer location and treatment duration. Among the three studies in which ulcers were located in the leg/foot, within-group heterogeneity was low ($I^2 = 0.0\%$, $P = 0.742$), and the ulcer healing rate in the electrical stimulation group was 20.62% higher than that in the control group (95% CI: 16.44%–24.80%). Among the six studies in which ulcers were confined to the foot, within-group heterogeneity was relatively high ($I^2 = 64.5\%$, $P = 0.015$), and the ulcer healing rate in the electrical stimulation group was 29.32% higher than that in the control group (95% CI: 18.33%–40.30%). There was no statistically significant difference between the two subgroups ($P = 0.147$).

The two studies with a treatment duration of 12 weeks showed no within-group heterogeneity ($I^2 = 0.0\%$, $P = 0.549$), with a WMD of 19.32% (95% CI: 13.57%–25.07%). The five studies with a treatment duration of 4 weeks showed low within-group heterogeneity ($I^2 = 22.6\%$, $P = 0.271$), with a WMD of 23.50% (95% CI: 17.43%–29.57%). The two studies with a treatment duration of 8 weeks showed high within-group heterogeneity ($I^2 = 86.4\%$, $P = 0.007$), with a WMD of 36.46% (95% CI: 10.27%–62.66%). There was no statistically significant difference among the subgroups ($P = 0.330$). To systematically address and explore the sources of any identified significant heterogeneity, subgroup analyses (e.g., by treatment duration or ulcer location) and sensitivity analyses (e.g., leave-one-out analysis) were utilized.

Sensitivity analysis To verify the robustness of the meta-analysis results, sensitivity analysis was performed using the leave-one-out method. After excluding each study in turn, the point estimate of the pooled effect size fluctuated approximately from 18.07% to 33.23%, all of which were close to the overall pooled effect size of 24.81%. Moreover, neither the direction nor the statistical significance of the pooled effect changed, indicating that the meta-analysis results were relatively robust and were not unduly influenced by any single study.

Country(ies) involved China.

Keywords electrical stimulation; diabetic foot; ulcer; wound healing; meta-analysis.

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