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TITLE Do non-weight bearing interventions improve healing of diabetes related foot wounds when compared with knee high off-loading devices? A systematic review and meta-analysis.

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ABSTRACT (maximum 450 words. Please use the following or similar headings: Background/Methods/Results/Conclusions)

Background: Diabetes Related Foot Ulcers (DFU) can be challenging to treat, and those living with DFU's have increased morbidity and mortality risk.1 Management of plantar DFU's involves minimising wound pressure, with guidelines recommending knee-high off-loading devices.2 Few studies directly compare various non-weight bearing methods and knee-high devices for DFU healing. Therefore, we aimed to conduct the first proportional meta-analysis to compare the effectiveness of DFU healing between NWB and knee-high offloading devices

Method: A systematic literature review using PubMed, Medline, Web of Science, Scopus and CINAHL databases was undertaken on 16/09/2024. PROSPERO registration: CRD42024572156. Covidence was used to review and extract data from studies that assessed DFU healing time and/or the proportion of wounds healed using knee-high offloading devices or methods that aimed to achieve NWB or focal wound site NWB. Removable and non-removable subgroups were also compared. Using R Studio, a meta-analysis of means compared healing time (days) and a proportional meta-analysis compared the number of DFU's healed between groups at 12 weeks/study conclusion. A 21-question scoring system for DFU studies, assessed study quality.3

Results: 423 studies were screened by title and abstract, leaving 85 screened using full-text and 58 studies included. 15 studies (7 non-removable cohorts, 13 removable cohorts) contained NWB offloading and 684 participants, whilst 43 studies (44 non-removable cohorts, 18 removable cohorts) and 1907 participants assessed knee-high offloading (see Table 1).

Table 1: Outcomes

Mean healing time was significantly less in the knee-high group compared to NWB, although proportions of wounds healed were similar at both time points. However, from studies that reported baseline wound duration (NWB=4, knee-high=17), NWB wounds were of significantly higher chronicity, likely contributing to slower healing time. Intervention removability did not affect wound healing.

Conclusions: Insufficient evidence exists to support NWB over knee-high offloading for DFU healing, with comparable outcomes observed between removability subgroups. No randomised controlled trials (RCTs) have directly compared non-removable NWB with non-removable knee-high offloading, highlighting the need for further research. Future studies should control for wound chronicity and include measurements of activity and adherence. Ultimately, well-designed RCTs are required to determine whether NWB can improve DFU healing.

1. Armstrong DG et al. (2020). J Foot Ankle Res, 13(1).
2. Bus SA et al. (2024). Diabetes Metab Res Rev, 40(3).
3. Jeffcote, WJ et al. (2016). Lancet Diabetes Endocrinol, 4(9).

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Table 1: Outcomes

	Mean Healing time (days)	Proportion Healed 12 weeks	Proportion Healed Study Conclusion	Mean Healing time (days) Non-removable	Mean Healing time (days) Removable	Baseline Wound Duration (days)	Quality Assessment (Mean score/21)
NWB	86.21 (95% CI 69.37-103.05)	65%	72%	47.78 (95% CI 41.03-54.54)	96.93 (95% CI 76.67-117.19)	541.5	14.53
Knee-high	55.96 (95% CI 48.05-63.87)	73%	75%	49.61 (95% CI 42.95-56.27)	79.39 (95% CI 59.42-99.36)	176.8	14.00
Significance p<0.05	p=0.0014	p=0.5091	p=0.7096	p=0.1522	p=0.2268	p=0.038	p=0.592