

Mechanical Validity of Randomised Controlled Trials Supporting the 2023 IWGDF healing of foot ulcers Recommendations: A Meta-Research Audit



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Aim: Mechanical offloading is a core determinant of DFU healing, yet variability in application may introduce unmeasured co-intervention bias in advanced therapy RCTs. This study aimed to evaluate and quantify the mechanical offloading methodological robustness of RCTs cited in the 2023 IWGDF interventions to enhance healing recommendations.

Methods: A meta-research audit was conducted on 43 RCTs cited in the guideline on interventions to enhance diabetic foot ulcer healing. Trials supporting recommendations 9, 12, 13, 20, 23, and 28, with wound healing as a primary endpoint, were included).

Table 1: Offloading Quality Score System.

Domain	Score = 0	Score = 1	Score = 2
Device fidelity	Not reported or clearly inconsistent	Reported but suboptimal	Fully aligned with IWGDF recommendations
Monitoring strategy	No monitoring of adherence or activity	Subjective monitoring	Objective monitoring
Protocol symmetry	Not reported or clear asymmetry	Partially described or unclear	Clearly defined and equivalent
Implementation standardisation	No protocol described	Protocol mentioned but not detailed	Clearly defined and standardised
Applicator expertise	Not reported	Mentioned but without detail or standardisation	Clearly reported training and standardised

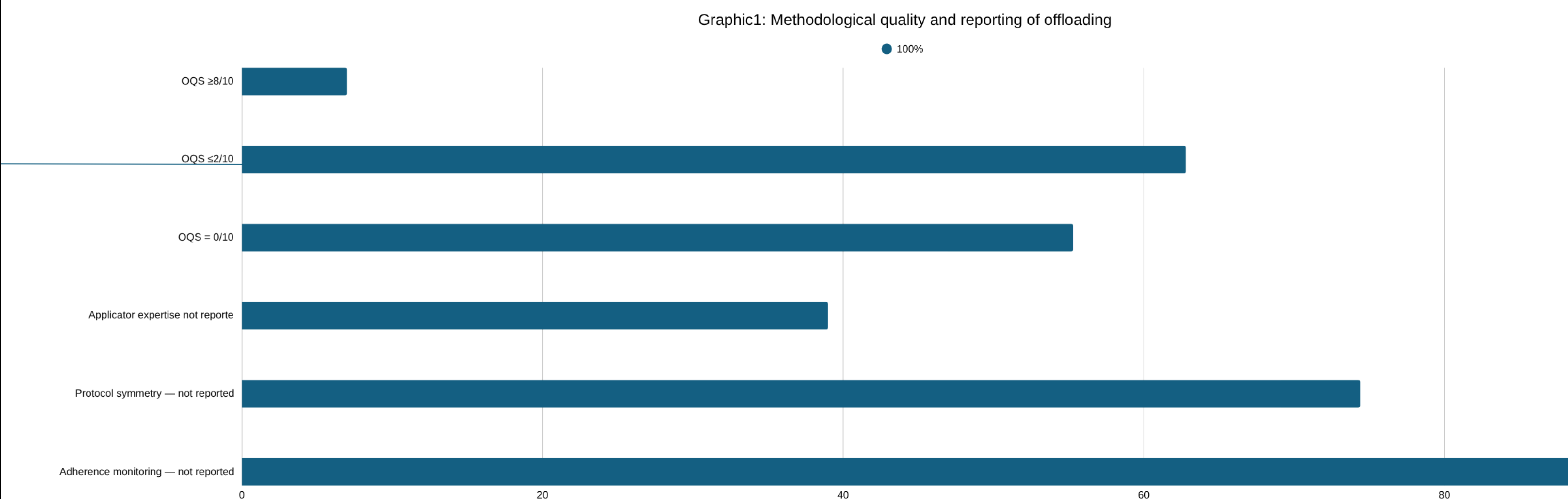
OQS = 5 domains × 0–2 points → Total score 0–10. Cohen’s kappa coefficient (κ = 0.89)

Results:

Table 2: Offloading type and OQS.

Offloading type	n (%)	OQS – range	Mean OQS
Removable	11 (25.6%)	3–8	4.6 ± 1.4
Non-removable	3 (7.0%)	5-10	8.3 ± 2.9
Mixed	7 (16.3%)	0–5	—
Not specified/mentioned	22 (51.2%)	0–1	—
Total	43 (100%)		2.1 ± 2.8

Non-parametric comparison (Non-removable vs. Removable): Mann-Whitney U = 29.5, p = 0.041; Hedges' g = 2.02 (massive effect size)



Conclusions: Most RCTs underpinning the 2023 IWGDF recommendations demonstrated limited reporting and standardization of mechanical offloading. The use of non-removable devices was identified as the only significant predictor of higher OQS ($\beta = 0.82$, $p < 0.001$). **Future DFU RCTs must mandate standardized offloading protocols and objective adherence monitoring to ensure internal validity.**