COMMENT ON CREWS ET AL.

Role and Determinants of Adherence to Off-loading in Diabetic Foot Ulcer Healing: A Prospective Investigation. Diabetes Care 2016;39:1371–1377

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We read with great interest the article by Crews et al. (1), which investigated the role and determinants of adherence to off-loading in diabetic foot ulcer healing. The authors found that greater off-loading adherence contributes to better ulcer outcomes and that postural instability is a key barrier to nonadherence. As the authors rightly stress, adherence to wearing an off-loading device is considered of great clinical importance; yet, research to substantiate this has been lacking. We congratulate the authors on this important study and particularly their use of a validated method to measure adherence. However, we want to address three aspects that limit broader interpretation.

First, the primary clinical outcome chosen was ulcer area reduction at 6 weeks. Although predictive of ulcer healing, it is a surrogate clinical outcome; the recommended outcome to be reported is ulcers healed by a fixed time, with 12 weeks used in most studies (2,3). A reason for using this surrogate outcome is not provided. It may be that the adherence monitor could only measure for a limited time period, judging by the mean use of 35 days. Yet, even without measuring adherence for the full treatment period, reporting the recommended outcome of healing at 12 weeks would have allowed for direct comparison with similar studies on off-loading (3).

Second, only baseline participant characteristics (Table 1 in ref. 1) and β-coefficients of predictors of ulcer healing and off-loading adherence from multivariate models (Tables 2 and 3 in ref. 1) are reported. Again, this article may have been enhanced and allowed a better comparison with other studies if univariate and multivariate regression results for all baseline characteristics were reported as well.

Third, objective measurements of plantar pressure were not conducted. In this study, different off-loading devices were used, with the majority of participants (77%) using a removable cast walker. Subgroup results of the different devices would have increased our understanding of their effect on outcomes. However, with the great variation in foot morphology in people with diabetic foot ulcers, the foot-device interface always differs across patients. As diabetic foot ulcer healing depends on the reduction of mechanical stress at the ulcer site, plantar pressure and the variation thereof across patients may have impacted outcomes (4). Mechanical stress is likely to be a strong predictor in multivariate analysis of ulcer healing, and measuring this in addition to adherence would have further improved our understanding of the outcomes found. In our view, this should be standard in studies on off-loading adherence and ulcer healing (5).

In conclusion, we commend the authors for performing this much needed study on off-loading adherence and diabetic foot ulcer healing. We hope the authors can provide the following additional information (published as an online appendix) to address the three aspects discussed in this letter: 12-week healing outcomes, univariate and multivariate regression results for all baseline characteristics, and subgroup results on clinical and adherence outcomes for the different off-loading devices. Such information would further enhance the scientific merits of this article and enable better clinical interpretation and comparison with past and future studies.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

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