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Advanced Biological Therapies for Diabetic Foot Ulcers

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Objective To assess the clinical use of advanced biological therapies in treating diabetic foot ulcers in practice and the effect of these therapies on time to healing.

Design A retrospective cohort study.

Setting A validated wound care database from January 1, 2001, through December 31, 2004.

Participants Two thousand five hundred seventeen patients with diabetic neuropathic foot ulcers.

Intervention Patients who received advanced biological therapy (ie, Apligraf, Regranex, or Procuren).

Main Outcome Measure Time to healing after initial use of advanced biological therapy. This was derived using Kaplan-Meier estimates and the Ederer least squares method after adjusting for covariates, which were assessed using generalized estimating equations and Cox proportional hazards regression modeling.

Results Advanced biological therapy was used, on average, within 28 days from the first wound clinic visit and associated with a median time to healing of 100 days. Regardless of the advanced biological therapy used, wounds with larger wound area, more severe wound grades, longer duration of wound prior to the first visit, and prolonged time to treatment with advanced biological therapies were significantly associated with longer time to healing. Wounds treated with engineered skin as the first advanced biological therapy were 31.2% more likely to heal than wounds first treated with topical recombinant growth factor ($P < .001$), and 40.0% more likely to heal than those first treated with platelet releasate ($P = .01$). Wound size, wound grade, duration of wound, and time to initiation of advanced biological therapy affected the time to healing.

Conclusions Advanced biological therapies were used, on average, within 1 month, and improved healing of refractory diabetic foot ulcers. Differences on outcomes among advanced biological therapies were noted.