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ABSTRACT

Efficacy of placental derived allografts and standard of care in the treatment of nonhealing diabetic foot ulcers using matched controls: a randomized controlled trial

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Abstract

Diabetic foot ulcers (DFUs) are a severe complication of diabetes, contributing to high morbidity, risk of amputation, premature mortality, and substantial healthcare costs. Standard of care (SOC), including debridement, offloading, infection control, and moisture balance, remains the foundation of DFU treatment; however, many ulcers fail to achieve complete closure with SOC alone. Placental-derived allografts, classified as cellular, acellular, and matrix-like products (CAMPs), provide a biologically active extracellular scaffold rich in growth factors and struc-tural proteins that support angiogenesis, cellular migration, and control of inflammation. These properties suggest that CAMPs may overcome impaired healing pathways characteristic of chronic diabetic wounds. The RENEW trial is a multicenter, prospective, randomized controlled modified platform study designed to evaluate the effectiveness of multiple placental-derived al-lografts in combination with SOC using matched controls. Findings from RENEW aim to gener-ate high-quality evidence to guide integration of biologic therapies into clinical practice, improve healing rates, and reduce long-term complications of DFU.