Collagen Dressing in the Treatment of Diabetic Foot Ulcer: A Prospective, Randomized, Placebo-Controlled, Single-Center Study

Presenting Author:
Yoo Jung Park, MD

Additional Authors:
Yeokgu Hwang, MD, Kwang Hwan Park, MD, PhD, Jae Wan Suh, MD, Dong-Woo Shim, MD, Seung Hwan Han, MD, PhD, Jin Woo Lee, MD, PhD, Woo Jin Choi, MD, PhD

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Introduction/Purpose: Ulcer healing in the diabetic patients is challenging due to a prolonged inflammatory response, extracellular matrix degradation irregularities, and increased bacteria presence. Collagen components are fundamental to the process of wound healing and skin formation. Recently, collagen-containing wound dressings, which create a biological scaffold matrix, have been used in the treatment of diabetic foot ulcer (DFU). However, there is not enough evidence to support that 100% collagen dressing can replace the diabetic wound management. In this study, we examined the effectiveness and safety of a new collagen dressing material in the treatment of DFU.

Methods: This study was a prospective, randomized, placebo-controlled, single-center study conducted between November 2011 and September 2014. The inclusion criteria were type 1 or 2 diabetes, a ulcer size ≥ 1.0 cm² that did not exhibit signs of healing for 6 weeks, Wagner grade 1 or 2, and palpable pulses at the ankle. The assessments of DFU included size, microbial culture study, detailed description of DFU, and clinical photos. Patients in the study group were treated with a collagen dressing material (100% porcine type I collagen) and foam dressing, while patients in the control group were treated with only foam dressing. Dressing changes had been performed two or three times per week. Complete ulcer healing rate was evaluated as a primary endpoint and ulcer size were compared between the two groups as a secondary endpoint.
Results: Thirty patients were included in the final analysis (study group: 17 patients, control group: 13 patients). There were no significant differences between two groups regarding demographic factors and baseline DFU characteristics. The study group presented a higher rate of complete healing as compared to that in the control group [82.4% (14/17), 38.5% (5/13), respectively, P = 0.022]. At the last follow-up, ulcer sizes of the study group were smaller than those of the control group (P = 0.048). The Kaplan-Meier analysis for the complete ulcer healing also showed a significantly higher rate of complete healing in the study group (Hazard ratio = 3.0, log-rank P = 0.025). There were no adverse events related to the dressing materials.

Conclusion: This study supports that the wound dressing using 100% collagen materials may offer a safe and effective treatment for DFU.