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

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Introduction/Purpose: Fast and complete healing of a diabetic foot ulcer (DFU) is challenging due to the hostile wound healing environment of the diabetic patients. As a part of a multimodal treatment approach, advanced dressing material using hyaluronic acid (HA) has been found to be effective. However, previous studies have used HA with additional biologics, which interferes in determining the true clinical effect of HA in DFU. The purpose of this study is to examine the effectiveness and safety of a new HA dressing material in the treatment of DFU.

Methods: This study was a prospective, randomized, placebo-controlled, single-center study conducted between September 2012 and January 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 the DFU, and clinical photos. Patients in the study group were treated with an HA dressing material (hyaluronic acid 80 ± 5% and poloxamer 10 ± 5%), while patients in the control group were treated with a conventional moisture-retentive dressing (petrolatum gauze). Weekly follow-up was conducted with the dressing change up to maximum 12 weeks. Complete ulcer healing rate was evaluated as a primary endpoint. Additionally, healing velocity and the mean duration for achieving a 50% ulcer size reduction was compared between the two groups as a secondary endpoint.
**Results:** Twenty-five patients were included in the final analysis (study group: 13, control group: 12). There were no significant differences between two groups regarding demographic factors and baseline DFU characteristics. The study group presented a significantly higher complete healing rate as compared to that in the control group [84.6% (11/13), 41.6% (5/12), respectively, P = 0.041]. Faster ulcer healing velocity and shorter mean duration for achieving a 50% ulcer size reduction were observed in the study group (P = 0.022, P = 0.004, respectively). The Kaplan-Meier analysis for the median time for 50% ulcer healing rate also showed a significantly shorter duration in the study group (21 days vs 39 days, P = 0.012). There were no adverse events related to the dressing materials.

**Conclusion:** This study supports that a HA dressing without additional substances may offer a safe and effective treatment for DFU.