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Randomized Comparative Trial of a Collagen/Oxidided Regenerated Cellulose Dressing in the Treatment of the Neuropathic Diabetic Foot Ulcer

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Aim: To evaluate the efficacy of the collagen / oxidized regenerated cellulose (ORC) wound therapy on the healing rate of neuropathic diabetic foot ulcer (DFU) and to compare these results with a control group of patients treated with the center´s standardized protocol of good of wound care. **Methods:** 40 DFU patients, 33 males (80%) and 7 females (20%) with average age of 57±10 years and a history of neuropathic diabetic foot ulcer duration between 45 days and 17.1 years, were included in this comparative study and randomized to receive either the center´s standardized protocol of good wound care (n=20 patients) or the collagen / ORC wound therapy (n=20 patients). Dressing changes and the collagen / oxidized regenerated cellulose (ORC) replenishment happened every 48 hours. Both groups were then followed up for 6 weeks at 3 stages: day 0, day 21 and day 42. Wound sizes were evaluated using the Wagner and Texas classification. **Results:** After 6 weeks, complete healing was achieved in 12 patients (63% of n=19) in the collagen / ORC wound therapy group versus 3 patients (15% of n=19) in the control group ($p<0.03$). The mean time to healing was 23.3 +/-9.9 days in the collagen / ORC wound therapy group and 40.06 +/-1.15 days in the control group ($p<0.01$). **Conclusions:** Results confirmed the hypothesis that the use of a collagen / oxidized regenerated cellulose (ORC) in patients with neuropathic foot ulcers leads to better tissue regeneration than the center´s standardized good wound care. One important observation is that the tissue regeneration response was excellent in patients that previously underwent surgical debridement. Our findings support that the collagen / ORC wound therapy benefits this type of wounds because it increases the concentration of endogenous growth factors, which are highly altered in neuropathic diabetic foot ulcer patients, and prevents them from being degraded.