

**BILAYERED CELL THERAPY IN THE TREATMENT OF NEUROPATHIC DIABETIC FOOT ULCERS**

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**Aim:** A study of 72 subjects conducted in the European Union and Australia assessed the safety and efficacy of a bilayered cell therapy \* (BCT) composed of living keratinocytes and living fibroblasts in the treatment of non-infected, diabetic foot ulcers.

**Methods:** This prospective, multicentre, randomised, controlled, open-label study compared BCT used in conjunction with standard therapy (sharp debridement, standard wound care, and off-loading) against standard therapy alone. The design and patient population of this study were similar to a 208-subject United States trial (Veves, Diabetes Care, 2001).

**Results:** Safety results were comparable between the BCT and Control groups. In particular, through 12 weeks post-treatment, rates of treated ulcer infection (12.1% BCT, 12.8% Control), osteomyelitis (3.0% BCT, 0.0% Control), and amputation (no events in either group) were similar and showed no statistical difference.

For efficacy, 51.5% of BCT subjects achieved wound closure by 12 weeks post-treatment, compared to 26.3% of Control subjects ( $p=0.049$ ; Fisher's exact test). Kaplan-Meier curves similarly trended towards a shorter time to healing in the BCT group compared to the Control group ( $p=0.059$ ; log-rank test).

These results were markedly similar to the US study, where safety outcomes were comparable for BCT and Control groups, and multiple efficacy measures demonstrated statistical superiority of BCT.

**Conclusions:** Subjects treated with BCT had comparable safety and superior efficacy compared to Control subjects. These findings are similar to the US study, and thus corroborate the previous findings of safety and efficacy within an EU context.

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