**Abstract**

This study was a randomized, prospective, multi-center, open label study designed to test whether a topical, electrolyzed, super oxidized solution (Microcyn Rx) would be a safe and effective treatment for the treatment of mildly infected diabetic foot ulcers. These ulcers (n=67) were randomized into three groups. Wounds irrigated with Microcyn Rx alone were compared to patients treated with oral levofloxacin plus normal saline wound irrigation, and to patients treated with oral levofloxacin plus Microcyn Rx wound irrigation. Patients were evaluated on day 3, at the end of treatment on day 10 (EOT, Visit 3), and 14 days after completion of therapy for test of cure (TOC, Visit 4).

In the clinically evaluable population of the study, the clinical success rate at visit three (end of treatment) for patients treated with Microcyn alone was 77.8% compared to 61.1% for the Levofloxacin. At visit four (test of cure) for patients treated with Microcyn alone was 93.3% compared to 56.3% for the Levofloxacin plus saline---treated patients. This study was not statistically powered, but the high clinical success rate (93.3%) and the p-value (0.033) would suggest the difference is meaningfully positive for the Microcyn---treated patients.

In the microbiologically evaluable (ME) population at Visit 3, more patients in the groups receiving levofloxacin were classified as microbiological cures than in the Microcyn Rx alone group; however, no statistically significant differences among the treatment groups Draft 4 4 was observed. Microcyn Rx was safe and well-tolerated when administered with and without levofloxacin.

These data suggest that Microcyn Rx is safe and at least as effective as oral levofloxacin for mild diabetic foot infections. Additional controlled, statistically powered clinical trials will be required to confirm these results.