

## **Matrix protection therapy in diabetic foot ulcers: Pilot study evaluating the effect of CACIPLIQ20 on wound healing**

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### **ABSTRACT**

We aim to evaluate whether matrix protection therapy aids the management and the promotion of the healing of chronic wounds of lower extremity in diabetic patients. A total of ten diabetic patients with non-infected cutaneous chronic wounds were recruited among our patients undergoing best available moist environment treatment including control of their glycemia and foot discharge with a mean of 38 weeks with no sign of improvement (range 4-77wks). Each foot was its own control. CACIPLIQ20 was topically applied twice a week for 5 minutes and for a maximum of ten weeks.

Wound area measurements were repeated every week after starting treatment. Ulcer closure defined as 100% re-epithelialization. Average wound size assessed by planimetry was  $7.5 \text{ cm}^2 \pm 10 \text{ cm}^2$  (wound volume  $2.5 \text{ cm}^3 \pm 4.00 \text{ cm}^3$ ). All patients reacted and stagnant wounds started to improve rapidly with significant reduction in the mean wound area after one week ( $5.6 \pm 8.8 \text{ cm}^2$ ,  $p = 0.021$ ) and four weeks ( $4 \pm 8.6 \text{ cm}^2$ ,  $p = 0.001$ ) of treatment. At the 10 weeks final follow up, six patients healed (60% , primary end point) in an average time of 5.4 weeks and 3 remaining patients achieved a greater than 80% and one over 50% reduction in wound size (mean healed area after 10 weeks was  $9.4 \pm 7.6 \text{ cm}^2$ ). After this 10 weeks periods none ulcer-healed patients were no more treated by CACIPLIQ20 but received standard care. After 6 months one ulcer healed completely, the other ulcers remained stagnant. Although further investigations on the potential effects of this product on chronic wound healing are required, to our knowledge, no other product would have accelerated by at least sevenfold the closure of none-healing diabetic foot ulcers under normal care. CACIPLIQ20 based Matrix therapy offers as a simple and safe solution to break the endless cycle of long standing and costly chronic wounds.