

# PROMOGRAN<sup>®</sup>

## LEVEL ONE - RCT STUDY

### Randomized comparative trial of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers.

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#### KEY POINTS

- A RCT in neuropathic diabetic foot ulcers comparing **PROMOGRAN<sup>®</sup>** with standard of care (MWH) in 40 patients
- A significant difference in the number of wounds healed and time to complete healing was found when neuropathic diabetic foot ulcers were treated with **PROMOGRAN<sup>®</sup>** compared to control treatment (moist wound healing)
- **PROMOGRAN<sup>®</sup>** also resulted in a greater percentage reduction in wound size compared to control treatment. Wound size assessment included volume, area and ulcer depth

#### STUDY OBJECTIVE

To evaluate the efficacy of **PROMOGRAN<sup>®</sup>** in the treatment of neuropathic diabetic foot ulcers.

#### METHODS

Randomised, prospective, controlled, longitudinal, clinical trial in neuropathic diabetic foot ulcers

- 40 patients were enrolled, and followed for 6 weeks
- Patients were randomised into 2 groups; **PROMOGRAN<sup>®</sup>** (n=20) and control (n=20; standardized protocol for good wound care). The wounds in both groups were covered with **TIELLE<sup>®</sup>**, a moist wound healing dressing
- Wounds were evaluated using the Wagner and Texas classifications prior to the start of the study
- All wounds received decontamination therapy (**ACTISORB<sup>®</sup>**) prior to randomisation and wound dressings were changed every 48 hours

## RESULTS

Complete healing was achieved in 12/19 (63%) patients receiving **PROMOGRAN**<sup>®</sup> treatment compared with 3/19 (15%) patients in the control group ( $p < 0.03$ )

The mean time to achieve healing was 23.3 +/- 9.9 days in the **PROMOGRAN**<sup>®</sup> group compared with 40.06 +/- 1.15 days in the control group ( $p < 0.01$ )

The percentage reduction in ulcer size was greater in the **PROMOGRAN**<sup>®</sup>-treated group as compared to control.

PERCENTAGE REDUCTION IN ULCER SIZE FOR EACH GROUP			
	VOLUME	AREA	DEPT
<b>PROMOGRAN</b> <sup>®</sup>	83.3 ± 22.1	46.1 ± 27.14	83.5 ± 32
CONTROL	60.8 ± 22.5	26.1 ± 31	65.2 ± 22.6

## CONCLUSIONS

In this study, the use of **PROMOGRAN**<sup>®</sup> in patients with neuropathic diabetic foot ulcers demonstrates a superior wound healing response, with an increased number of wounds healed and a shortened time to healing compared to control treatment ( $p < 0.05$ ).