PROMOGRAN®

LEVEL ONE - RCT STUDY
Use of a protease modulating matrix in the treatment of pressure sores

KEY POINTS
- A RCT in pressure sores comparing effect of PROMOGRAN® to standard of care (MWH) in 80 patients
- In this study, PROMOGRAN® treated pressure sores was found to
  - Have a greater frequency of complete healing compared to control
  - Have a shorter mean healing time compared to control
  - Be more cost-effectiveness than control
- This study supports PROMOGRAN® usage as part of an overall strategy in the treatment of pressure sores, providing shortened healing times while also improving the overall management of these wounds

STUDY OBJECTIVE
To evaluate the use of PROMOGRAN® in the management of pressure sores (chronic tegumentary losses) in selected patients according to a standardized protocol.

METHODS
Randomised, prospective, controlled, clinical study in pressure sores
- 80 patients were selected, randomly divided into 2 groups, a PROMOGRAN® treated group (n=40) and a control group (n=40), which consisted of daily disinfection and viscose-rayon gauze soaked in white Vaseline. Wounds in both groups were covered with a hydropolymer dressing
- Treatment was only initiated when the wounds was cleansed (no necrosis and no infection) using surgical debridement and disinfection with PVP-I solution
- Patients with pressure sores were evaluated and classified according to the Norton scale
- All patients with complete healing underwent a 6-month follow-up
RESULTS

Complete healing was achieved in 36 (90%) PROMOGRAN®-treated patients compared to 28 (70%) control patients.

Time required to achieve a clean wound ranged from 1-6 weeks, after which time to complete healing ranged from 2-6 weeks for PROMOGRAN® treated wounds and 2-8 weeks for control wounds.

Cost effectiveness data:

<table>
<thead>
<tr>
<th>DRESSING NUMBER (range used)</th>
<th>Hospitalisation stay (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMOGRAN®</td>
<td>6-15</td>
</tr>
<tr>
<td>CONTROL</td>
<td>14-52</td>
</tr>
</tbody>
</table>

This represents a cost-effectiveness advantage for the PROMOGRAN®-treated group.

CONCLUSIONS

Study demonstrates a greater frequency of complete healing and shorter healing times in PROMOGRAN®-treated patients compared to controls.

In addition fewer dressings were needed, and shorter hospitalisation stays required with PROMOGRAN® treatment, demonstrating better cost-effectiveness.

The ease of use experienced with PROMOGRAN® allowed for home management, attaining a better quality of life for the patient.