

# Clinical evidence to support the appropriate use of silver dressings in wound care



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## ABSTRACT

**Introduction:** Controversy surrounds the use and cost effectiveness of silver dressings in clinical practice. The present study provides clinical evidence to support appropriate use of silver dressings.

**Methods:** Clinical studies included: a post-marketing surveillance study with pressure sores/venous leg ulcer/diabetic foot ulcer/traumatic wounds patients (n=12 444) treated with ACTISORB® SILVER 220; a randomised control trial (RCT) with diabetic foot ulcer patients (n=40) treated with PROMOGRAN PRISMA® or the standard of care; a RCT with venous leg ulcers/pressure ulcer patients (n=99) treated with SILVERCEL® or calcium-alginate dressings.

**Results:** Results from the ACTISORB® SILVER 220 post-marketing surveillance study showed that signs of infection reduced from 64.5% at baseline to 7.4% at final visit. In the PROMOGRAN PRISMA® RCT, all patients were protected from infection compared with the control group, where 33% patients were withdrawn due to infection (p=0.012). Of the patients who completed the SILVERCEL® RCT, 4/38 (10.5%) in the control group were treated with systemic antibiotics at the final visit compared with 0/40 receiving SILVERCEL® (p=0.053). Additionally, fewer wounds treated with SILVERCEL® developed a clinical infection over the four-week follow-up compared with the control group (33% vs. 46%; p=0.223).

**Discussion and conclusions:** There is a wealth of clinical evidence demonstrating the efficacy of silver-dressings in wound care. Silver-dressings can assist in controlling infection and enhance patient quality of life by management of infection-related complications and can help to progress the wound to a normal healing trajectory.

## ACTISORB® SILVER 220 CLINICAL DATA

### Study Design

- In a post-marketing surveillance study, data from five clinical studies were pooled and analysed; this was justified as a single protocol was used throughout.
- In total, 12 444 patients with a range of non-healing chronic wounds were treated with ACTISORB® SILVER 220 for up to 6 or 12 weeks, or until healed.
- Chronic wounds treated included: pressure sores, venous leg ulcers, diabetic foot ulcers and traumatic wounds.

### Results

- Approximately 60% of patients were female. The overall study population had a mean age of 67 years. Approximately 32% were diabetic and the median wound duration at enrolment was three months.

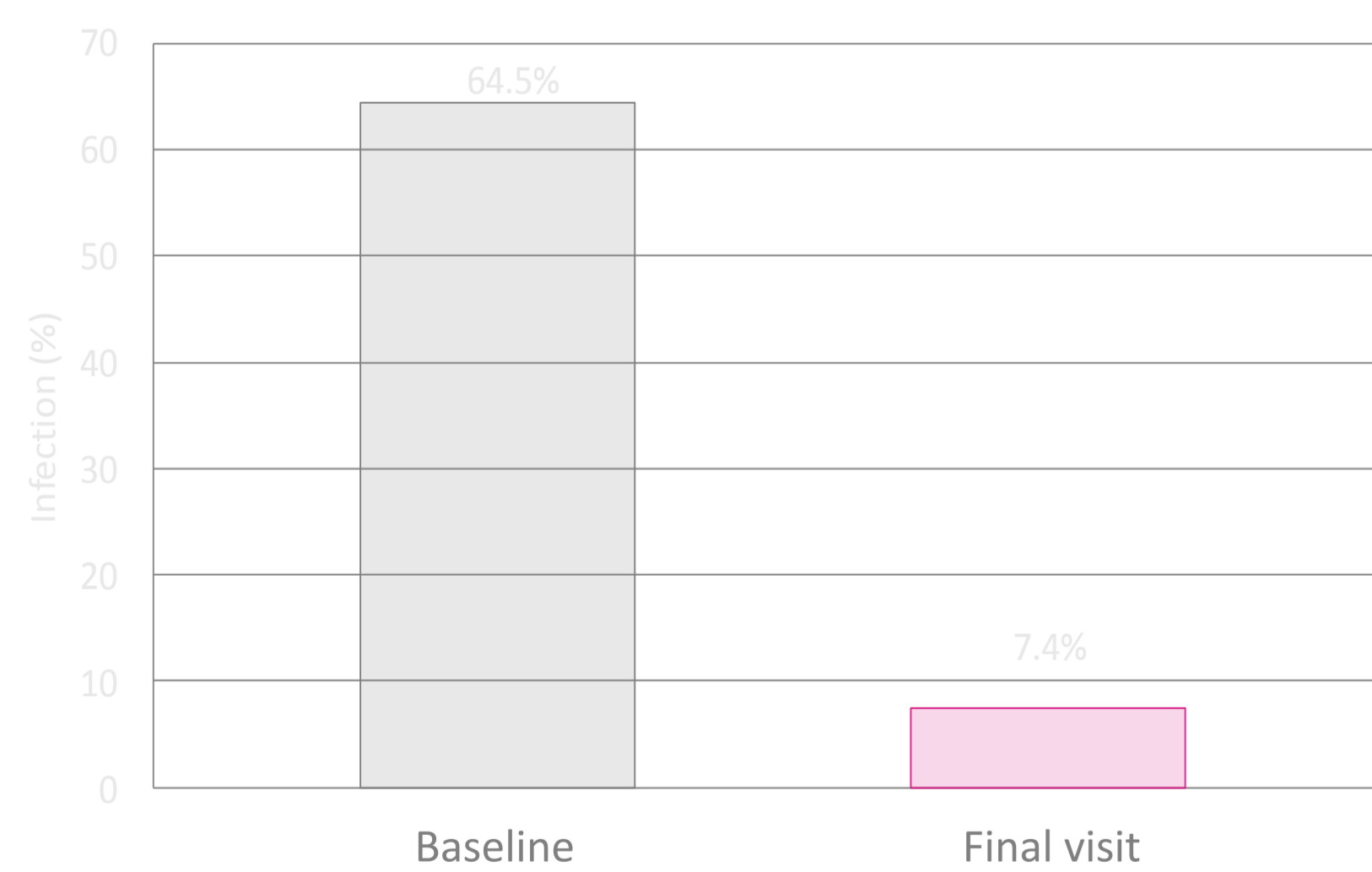


Figure 1. Signs of infection at baseline and at final visit in patients with chronic wounds treated with ACTISORB® SILVER 220.

- Overall, signs of infection reduced from 64.5% at baseline to 7.4% at final visit (Figure 1).
- The overall healing rate was 35.5% and 49.3% for 6 and 12 weeks treatment with ACTISORB® SILVER 220, respectively.

### Conclusions

- Clinical trials involving over 12 000 patients suggest that ACTISORB® SILVER 220 was effective at promoting wound healing, reducing wound malodour and safe.

### Reference

- White. A charcoal dressing with silver in wound infection: clinical evidence. Br J Community Nurs. 2001; 6(12 (Silver Suppl 2): 4-11.

## SILVERCEL® AND SILVERCEL® NON-ADHERENT CLINICAL DATA

SILVERCEL® and SILVERCEL® NON-ADHERENT are both antimicrobial alginate dressings. SILVERCEL® NON-ADHERENT contains the same silver-alginate material as SILVERCEL® but has an additional non-adherent ethylene methyl acrylate (EMA) wound contact layer. Clinical evidence for these silver-alginate based products are presented below.

### Study Design

- Patients with either a venous leg ulcer or a pressure ulcer (n=99) were randomised to receive treatment with SILVERCEL® (n=51) or a control calcium-alginate dressing (n=48) for up to four weeks. Assessments included completion of a modified ASEPSIS index to evaluate risk of infection.

### Results

- In total, 40/51 patients receiving SILVERCEL® and 38/48 patients receiving the control dressing completed the four-week study.
- Overall, 4/38 (10.5%) patients in the control group were treated with systemic antibiotics at the final visit compared with 0/40 patients receiving SILVERCEL® (p=0.053).
- Fewer wounds developed a clinical infection over the four-week follow-up in the treatment group (33% versus 46%; p=0.223).
- The 4-week closure rate was greater for patients receiving SILVERCEL® than the control treatment (0.32 +/- 0.57 cm<sup>2</sup> vs. 0.16 +/- 0.40 cm<sup>2</sup>; p=0.024).

### Conclusions

- Patients receiving SILVERCEL® were less likely to develop a clinical infection or require systemic antibiotics than those receiving a calcium alginate dressing.

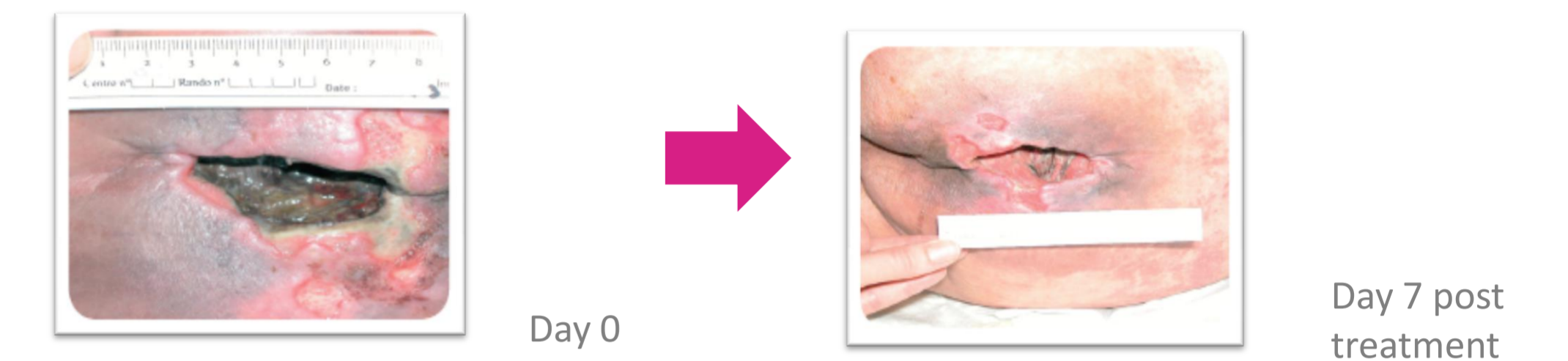
### Reference

- Meaume et al. Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection. J Wound Care. 2005; 14:479.

## Examples of wounds treated with SILVERCEL®

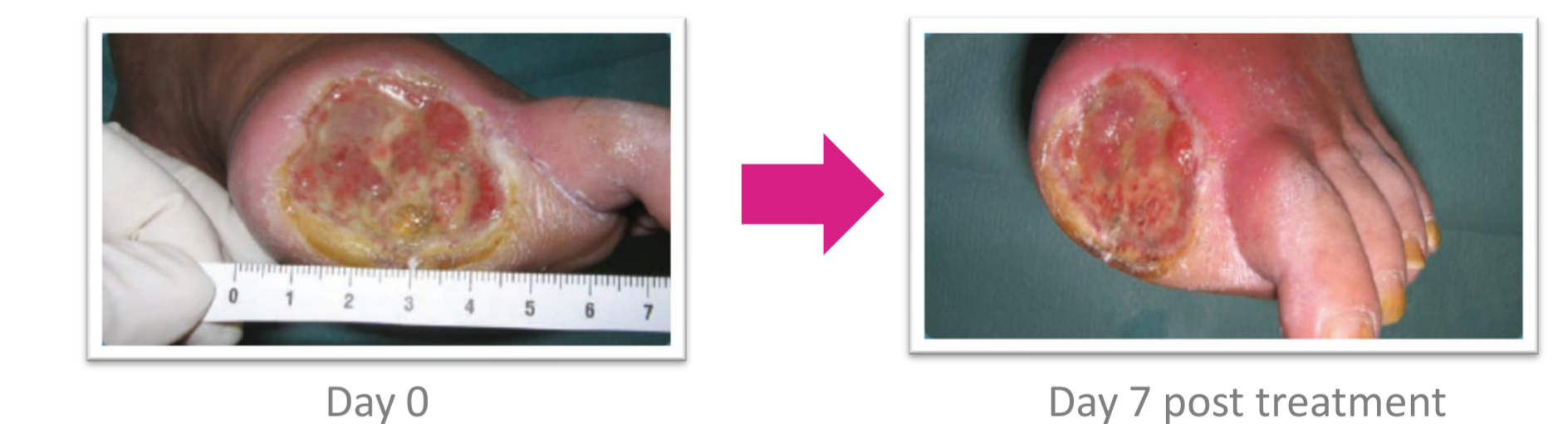
### Case Study 1:

93-year-old man with deep decubitus sacral ulcer (grade III) Patient also suffers from coronary insufficiency and Parkinson's disease Teot, L., Maggio, G., Barrett, S. The management of wounds using SILVERCEL hydroalginate: a case study series. Wounds UK 2005, 1(2):70-77.



### Case Study 2:

55-year-old male patient with a 4-year history of type 2 diabetes and concomitant angiopathy The patient has a critically colonised, post-amputation diabetic foot ulcer. Kingsley, A., Hoffman, H., Barrenscher, M., Magueija, C., Sharp, A., Eagle, M., Meaume, S., Antoninova, J., Schlosser, Clark J., Russell, F. SILVERCEL hydroalginate: a case study series. Wounds UK 2005, supplement 1(3).



## PROMOGRAN PRISMA® CLINICAL DATA

### Study Design

- Patients with diabetic foot ulcers (n=40) were randomised to receive either treatment with a PROMOGRAN PRISMA® (n=25) or the standard of care (SOC) (n=15) for 14 weeks. The percentage reduction in wound area from baseline determined.

### Results

- In total, 24/25 patients treated with PROMOGRAN PRISMA® and 15/15 patients treated with SOC completed the study.
- No wounds treated with PROMOGRAN PRISMA® were infected, compared with the control group where 33% patients were withdrawn due to infection (p=0.012).
- Significantly more patients had a >50% reduction in wound area (Margolis Index) at Week 4 with PROMOGRAN PRISMA® compared with the SOC (70% vs. 43%; p=0.035).

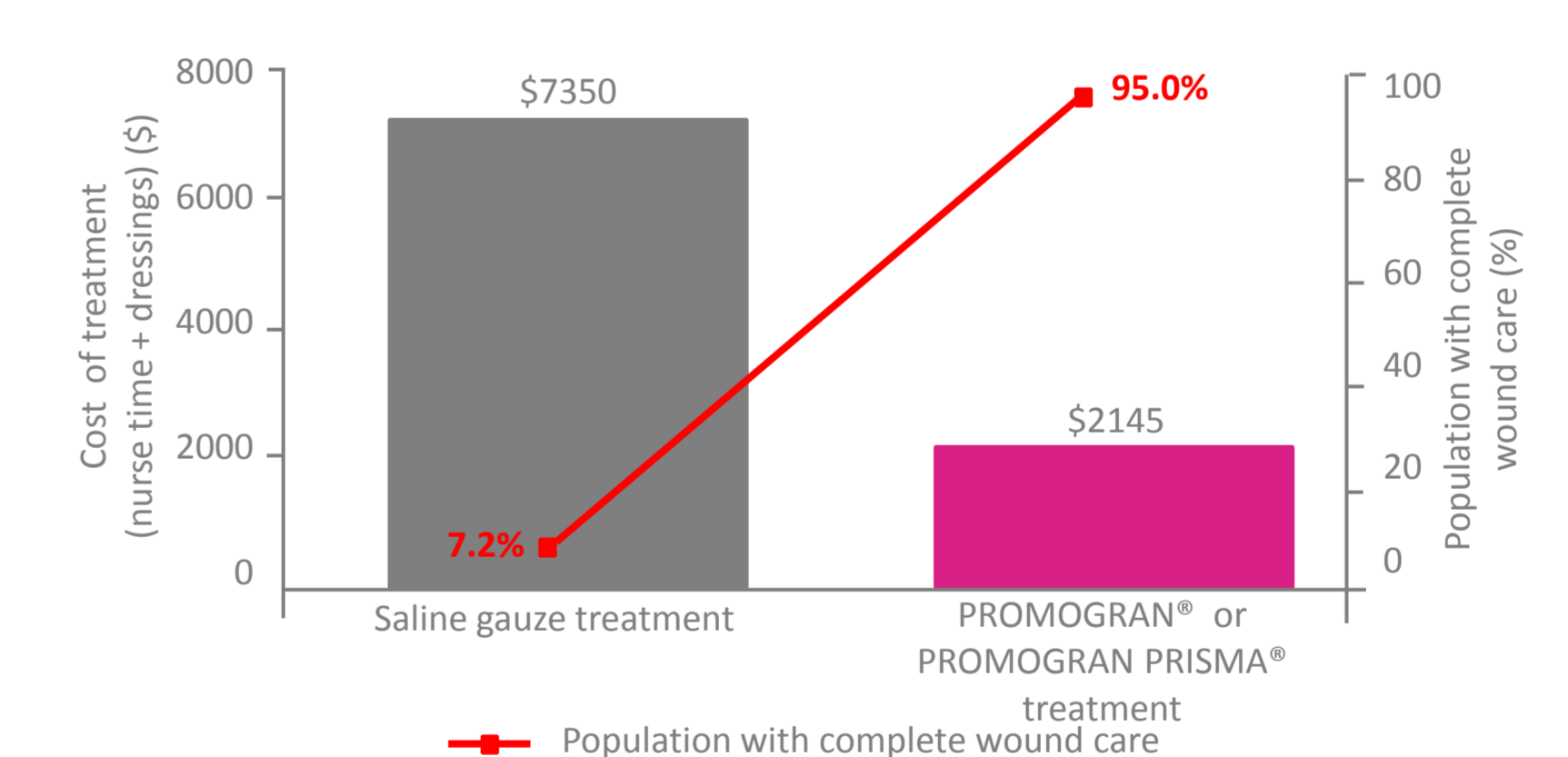
### Conclusions

- Clinical data suggests that PROMOGRAN PRISMA® stimulated healing while protecting the wound from infection.

### Reference

- Gottrup et al. Comparative clinical study to determine the effects of collagen/ORC + silver therapy on wound healing of diabetic foot ulcers. Presented at EWMA 2010.

## Cost and healing over two months of treatment



- In a retrospective study, 873 and 101 patients with chronic wounds received PROMOGRAN® or PROMOGRAN PRISMA®, or a gauze dressing, respectively.
- After two months of treatment, 95.0% of the PROMOGRAN® or PROMOGRAN PRISMA® treated wounds closed at a total cost of \$2145, compared with 7.2% of the saline gauze-treated wounds at a total cost of \$7350; 43% of saline-treated wounds healed by six months at a total cost of \$22050 (Snyder. OWM 2010; 56 [11A]: 9-15).

## SUMMARY

- Data presented in these selected clinical studies provides clinical evidence to support the appropriate use of silver-dressings.
- Data presented here is consistent with other clinical studies and *in vitro/vivo* work. Further clinical and *in vitro/vivo* evidence to support the use of silver in wound care can be found at <http://www.systagenix.com>
- Silver-dressings are cost effective, can assist wound healing and enhance patient quality of life.