

The effect of a silver impregnated activated charcoal dressing on delayed-healing wounds: - analysis of open, multi-center, observational studies



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PURPOSE

Between 1996 and 2000, five separate clinical (observational) studies were conducted in Germany to assess the effectiveness of a silver impregnated activated charcoal dressing in the general population¹.

TEST DRESSING

The silver impregnated activated charcoal (SIAC) dressing used in these studies was ACTISORB[®] Silver 220, manufactured by Johnson & Johnson Wound Management Worldwide, a division of ETHICON, INC.

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METHODOLOGY

Setting: Multi-center studies (general practitioners, dermatologists, surgeons), both in-patients and out-patients in Germany.

Methods: Four studies included a six-week follow-up assessment (patients in one study JJ13 [n=1753] were assessed at 12 weeks). All collected most of the same efficacy and safety data, allowing the results to be pooled. Lack of efficacy of previous treatments was the primary reason for initiating treatment with SIAC (83% patients). The majority (75.6%) of all wounds were being treated with ointments and gauze prior to entry into the studies.

Assessments were made at baseline and at the final visit.

PATIENTS STUDIED

A total of 12,444 patients were treated with SIAC. The type of wounds that were treated in these studies included:

- leg ulcers (7,798)
- diabetic foot ulcers (1,493)
- pressure ulcers (2,435)
- other wounds (718)

The 'other' category included mainly traumatic or post-surgical wounds.

Leg ulcers were venous (67%), arterial (3%) and the remainder mixed (30%). Diabetic foot ulcers were neuropathic in 58% of the cases and 42% were due to peripheral arterial disease. Pressure ulcers were 14% Grade I, 47% Grade II, 32% Grade III, and 7% Grade IV. Wounds were present on average 9 ± 38 months before treatment, however, leg ulcers were present on average 12 ± 43 months.

Figure 1: Mean wound area at baseline and final visit after use of SIAC for 6 or 12 weeks

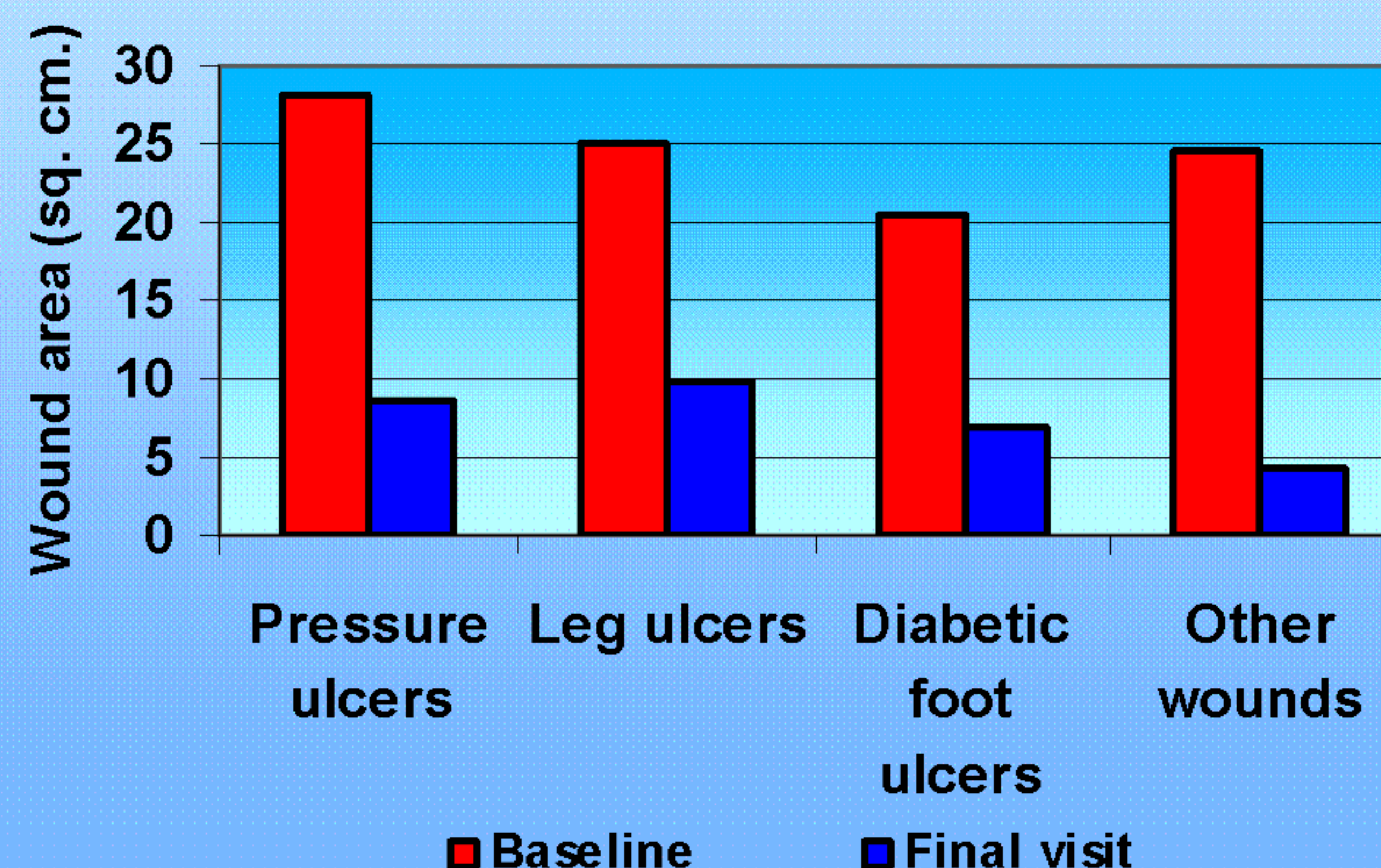
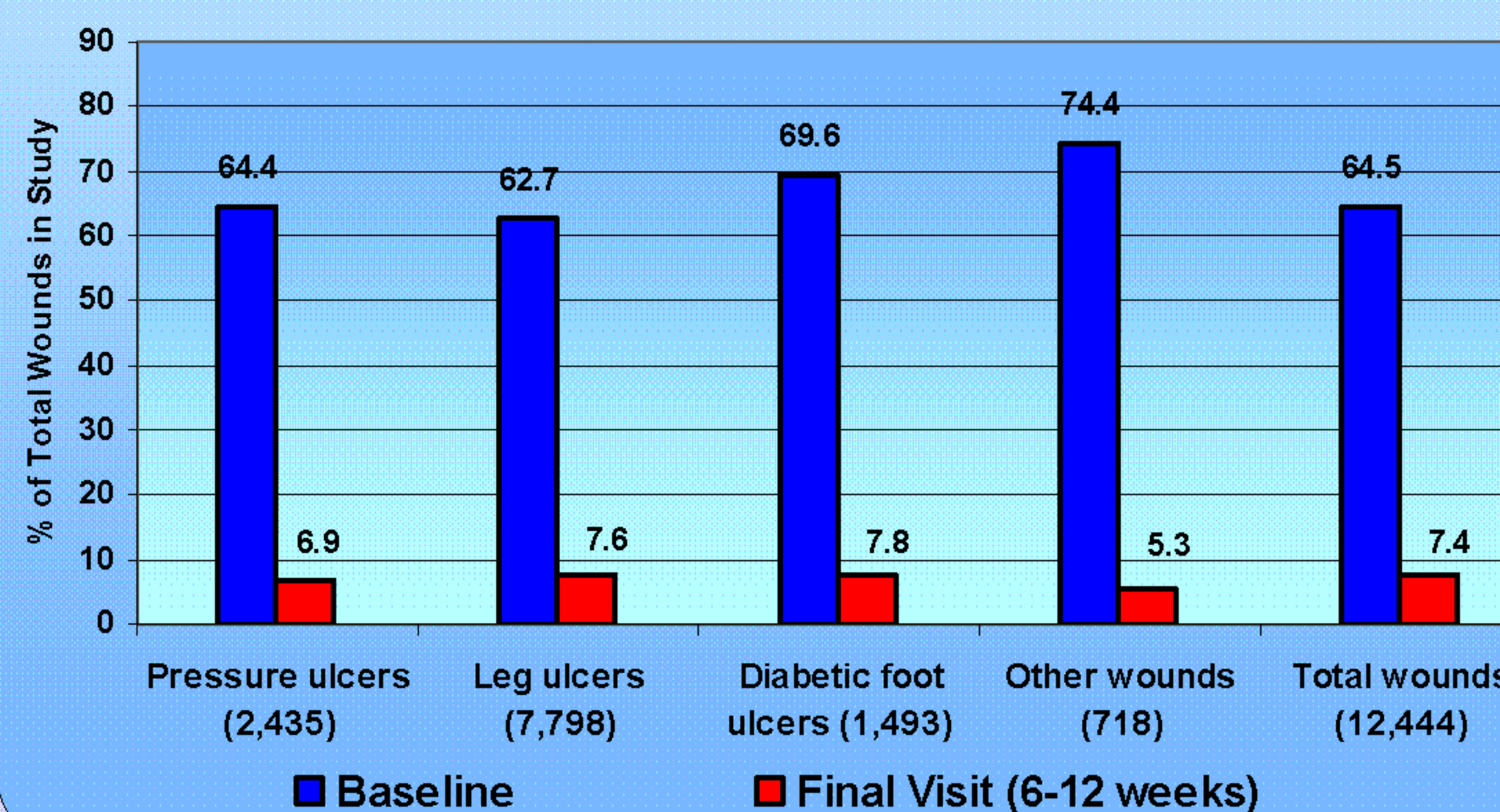


Figure 2: Signs of infection detected during use of SIAC over a 6 or 12 week period



RESULTS

Improvements were seen in all areas of wound healing following treatment with SIAC. Overall:

- 40.7% of all wounds were healed by the final visit,
- 54.1% were assessed as being improved,
- 3.9% as unchanged,
- 1.3% worsened.

There was a significant reduction in wound area by the last visit, regardless of the etiology of the wound (Figure 1).

Significant improvements were also seen in all wound characteristics, for all wound types, after treatment with SIAC in the percentage of wounds categorized as deep/pouch, displaying signs of infection, having moderate to high exudate, moderate to strong odor, presence of extensive necrotic tissue, and extensive fibrinous deposits.

Whilst improvements were seen in all characteristics, they were most significant in two specific areas, namely, reduction in the signs of infection and reduction in wound odor. At baseline 64.5% of wounds exhibited signs of infection compared to only 7.4% at the last visit (Figure 2).

As a result of the significant reduction in signs of infection, there was also a marked decrease in the concomitant use of local treatments for treating infections in patients in these studies. At baseline only 17.7% of all wounds did not require concomitant use of local treatments aimed at treating infection. By the final visit, this percentage had increased to 80.4%.

For wound odor, 42% of all wounds exhibited moderate to strong odor compared to only 3.6% of non-healed wounds at the final visit.

Regarding tolerability, a prevalence of local side-effects (dressing related or not) of 3.0% was recorded.

The overall opinion of the Investigators on the SIAC dressing was scored as 'excellent' in the majority of cases.

CONCLUSION

The results of the experiences of 12,444 patients pooled together from five observational clinical studies, demonstrate that the ACTISORB Silver 220 dressing provides excellent clinical results in the treatment of wounds with delayed healing.

REFERENCE

¹ Part of this study was presented as an oral presentation at the 12th European Wound Management Association meeting, Granada, Spain, 2002. Presenter: Professor Rudolf Stadler from Klinikum Minden, Hautklinik, Portastraße 7-9, 32423 Minden, Germany.