Results of a national multicenter observational trial on slough and debris removal properties on wounds at risk or with signs of a local infection with a highly negatively charged fiber dressing with silver*

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OBJECTIVE

A description of wounds treated with a highly negatively charged silver dressing (with technology lipido-colloid with silver ions, TLC-Ag, also called the poly-sorbent dressing with silver), and evaluation of the short-term clinical impact of the dressing on the wound healing process, under real-life conditions.

METHODS

A large, prospective, multicenter, observational study of 2270 patients in 81 centers in Germany, presenting with an exuding wound at risk or with clinical signs of local infection for whom the negatively charged dressing, has been prescribed. Main outcomes included:

- Primary judgment criterion: Evolution of wound surface area after max. 4 weeks of treatment
- Secondary judgment criteria:
  - Slough reduction
  - Tolerability
  - Acceptability

RESULTS

- A total of 2270 patients with acute and chronic wounds of various etiologies from 81 centers were treated with negatively charged dressing for a mean duration of 22±13 days.
  - 2,270 patients in outpatient care 81 centers in Germany
    – Figure 1A shows the type of wounds in the study, with diabetic, venous, abrasion, and postoperative wounds dominating.
  - Mean duration of the wounds: 43.4 (± 136.7) days; median 10 days
  - Mean observation period: 22.2 days
  - Three visits (baseline, interim, final for all measurements)
  - Mean dressing changes: 2.5 (± 1.2) per week.
  - At baseline, 318 patients (14.0%) already had a diagnosed wound infection and 1310 (57.7%) had at least one of the five pre-suggested clinical signs of infection (malodor, spontaneous pain, localized edema, erythema, and friable tissue granulation).
- Figure 1B shows a mean wound area reduction of 72.6% during the study on all wounds, acute, chronic, and unclassified.
- Acute wounds: Clinical improvement in wound healing was reported in 98.9% of acute wounds, with a wound closure rate of 68.5%.
- Chronic wounds: In chronic wounds, a median rate of wound area reduction of 57.4% was achieved, with an improvement in healing process documented by clinicians in 90.6% of cases, stabilization in 6.1% and worsening in 3.2%.
- Similar results were reported, **regardless of exudate level and proportion of sloughy and granulation tissues in the wound bed at baseline.**
- The fact that equivalent results are obtained with wounds **with and without slough** is unusual and seems to be specific to the negatively charged silver dressing that cleanses the wound during exudate management. This conclusion is based on the historical knowledge that ***slough delays wound healing***, even when other advanced dressings are used for exudate management.
- Figure 1C shows the average healing rate per wound category. As could be expected, chronic wounds have a lower healing percentage than the acute wounds.
- Slough/necrotic tissue at presentation is shown in Figure 2A, 61.2 % of patients presented with yellow or black slough/necrotic matter in the wound.
- **All wound types showed a reduction of sloughy tissue and an increase of granulation tissue. Overall, the proportion of sloughy tissue decreased from 48+/-26% at baseline to 22+/-23% at the final visit (Figure 2B)**
- All clinical signs of local infection and the diagnosed wound infections were substantially reduced at two weeks after the treatment initiation (Figure 3) and continued to decrease over the course of the study.
- There was reduction in evolution of exudate levels in acute, chronic, and unclassified wounds (Figure 4).
- The exudation was reduced compared to initial visit in 63.8% of all patients; 57.6% of wounds showed no exudate in final visit (Figure 5).
- The dressing was well tolerated and well accepted by both patients and health professionals
- By almost equal percentages (70-80%) physicians stated both the factors of slough removal, and the ability to manage local infection were their criteria in choosing the new negatively charged fiber dressing (Figure 10).

FIGURE 1A

Type of treated wounds

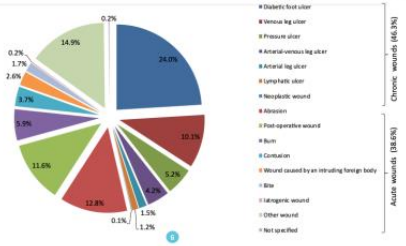
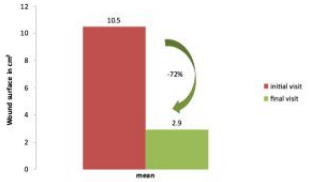
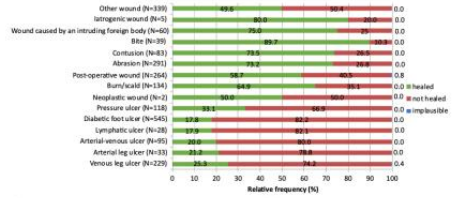


FIGURE 1B **Wound surface reduction**



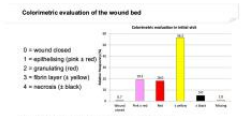
→ Mean wound surface reduced from 10.5 cm² to 2.9 cm²

FIGURE 1C **Healing rates**



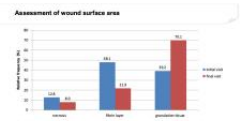
→ Healing rate varied between 17.8 and 89.7%

FIGURE 2A



→ In initial visit, most wounds (56.2%) were mainly yellow (only one answer possible)

FIGURE 2B



→ At baseline, slough was recovering 48.1% of the wound bed surface area and decreased to 21.9% at the end of the follow-up.

FIGURE 3

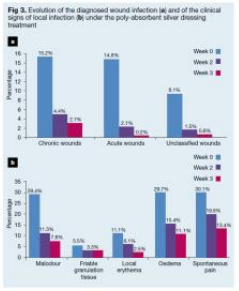


FIGURE 4

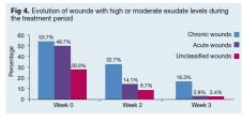
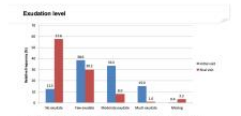


FIGURE 5



→ The exudation was reduced compared to initial visit in 63.8% of all patients; 57.6% of wounds showed no exudate in final visit

CONCLUSION

These results, documented in a large cohort of patients treated in current practice, support, and complete the clinical evidence on the healing properties and safety profile of the negatively charged silver dressing in the management of wounds at risk or with clinical signs of local infection, regardless of wound and patient characteristics. It is truly a dressing meant for "all types of wounds" and an unusual one in its ability to heal wounds with and without slough due to its observable properties of desloughing unique to the product that contains supercharged fibers.

*Urgoclean Ag

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