Confirmation of the safety and performance of a silver alginate[1] wound dressing and rope within the certified indications in routine clinical practice

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[3]Dermatologist (Kalyves, Greece)

[1]Suprasorb® A + Ag – Lohmann & Rauscher GmbH & Co. KG

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AIM:

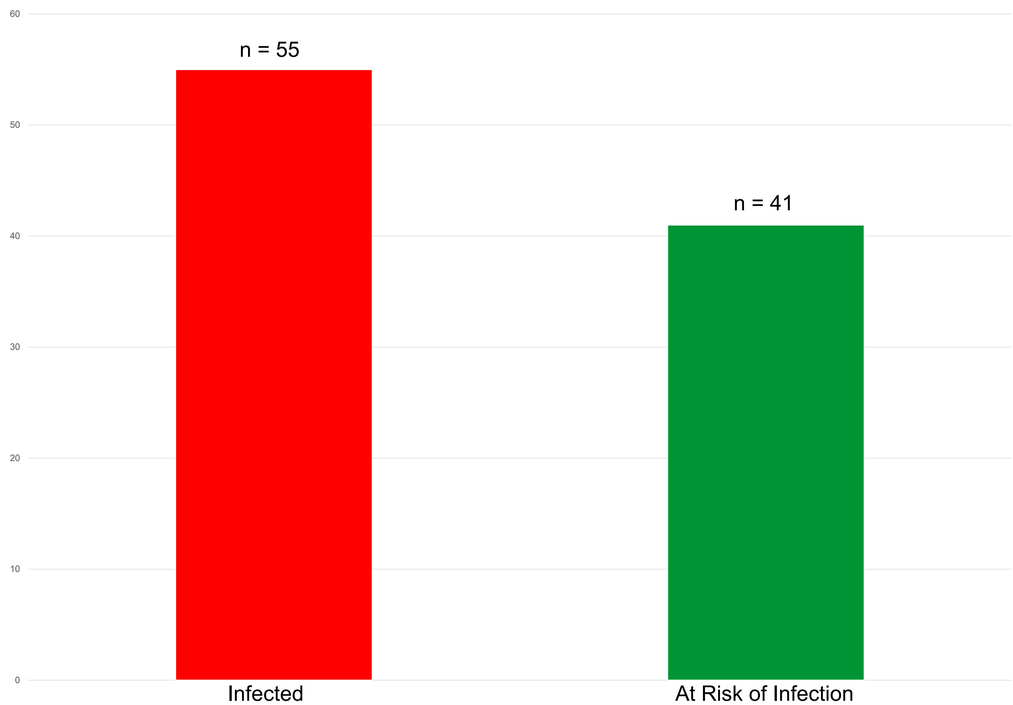
The objective of this study was to confirm the safety and performance of a silver alginate[1] wound dressing in the treatment of infected wounds and wounds at risk of infection.

METHOD:

The study was conducted as multicentre, open, single-arm cohort Post Market Follow-up study on patients presenting wounds at risk of infection or infected wounds. 99 patients across 11 centres in Poland were treated with a silver alginate[1] wound dressing according to clinical routine. Three visits were performed at d0, d10±3 and d21±3. As primary endpoint the **reduction and prevention of local wound infections** were assessed. Secondary endpoints comprised (serious) **adverse events** and **improvement of wound bed condition parameters** (e.g., exudate management, pain, surrounding skin, odour etc.). Recruitment period was from 09/2022- 12/2023. The study was registered at ClinicalTrials.gov (NCT05646121) and was approved by the ethical committee and polish competent authority.

GRAPH 1: Type of wounds

55 subjects were enrolled with infected wounds based on TILI scale (44 in per protocol population).
41 subjects were enrolled with wounds at risk of infection based on W.A.R. score (35 in per protocol population).



Included wounds:

- Venous lower leg ulcers
- Diabetic ulcers
- Post operative wounds
- Arterial ulcers
- Pressure ulcers

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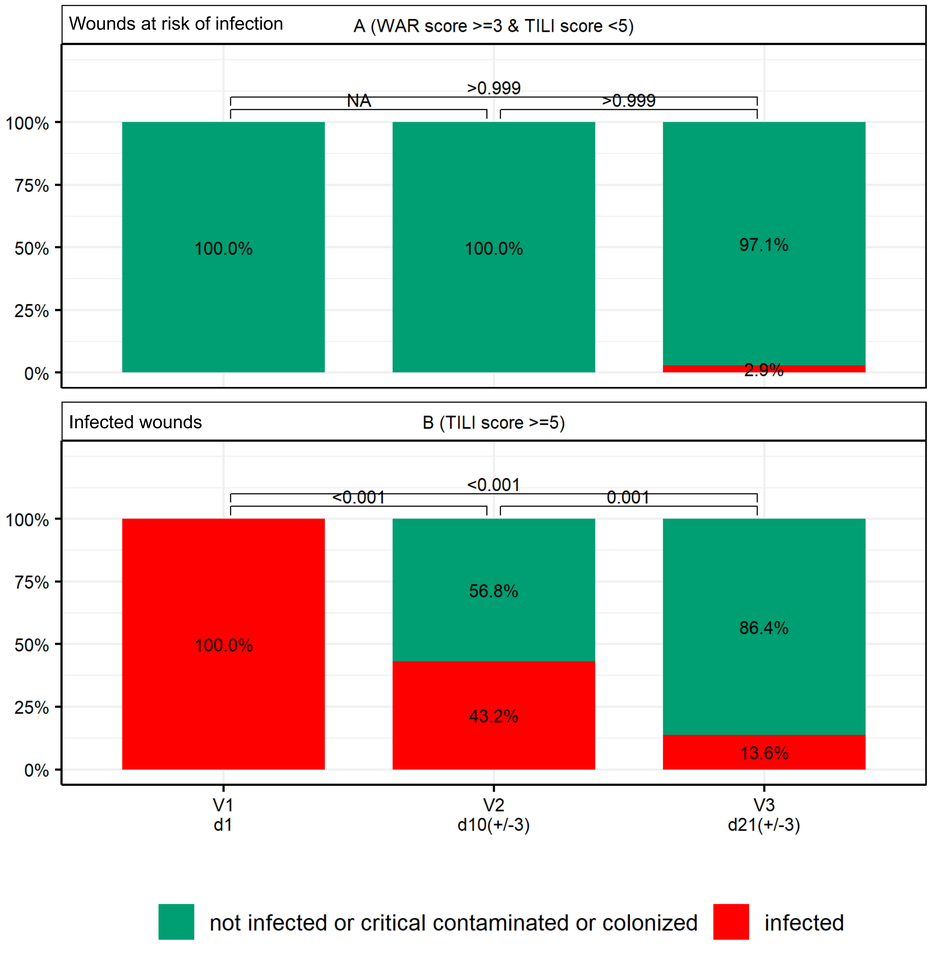
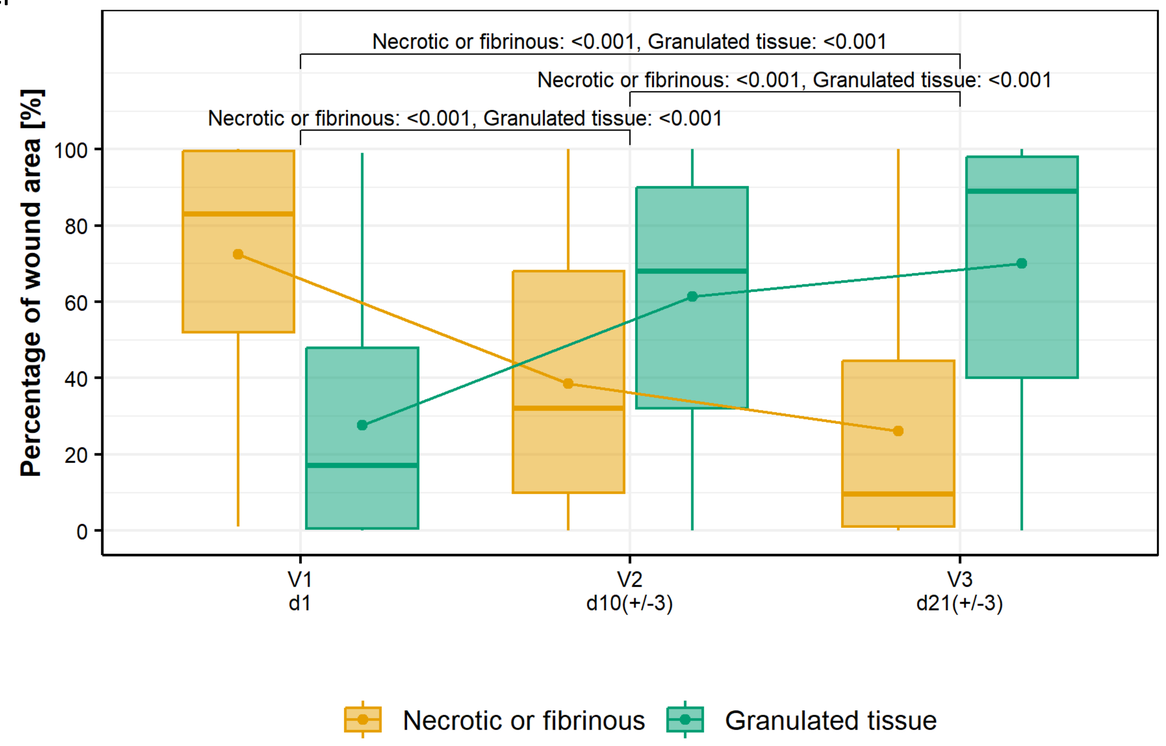
RESULTS:

The **number of infected wounds significantly decreased**. Corresponding to this, a wound shift was visible with a **significant increase of granulated tissue** and a **significant decrease of necrotic and fibrinous tissue**. Statistically significant onset was already visible **after 10 days** of treatment. Regarding safety aspects, no device deficiencies or adverse events with a clear relationship to the study procedure or study product were reported.

GRAPH 2: Infection

In the group of wounds at risk of infection 97.1% (95.29% CI 84.9 - 99.9%) remained uninfected at V3. In the group of infected wounds after 10 days 56.8 % and after 21 days 86.4% (95.29% CI 72.5 - 94.9) were not infected anymore. (Per protocol population)





GRAPH 3: Wound Shift

Fibrinous tissue reduced from 83.5% (d0) to 34.5% (d10±3) and 9.0% (d21±3) while granulated tissue increased from 16.5% (d0) to 65.5% (d10±3) and 89.0% (d21±3). All changes were statistically significant after 10 and 21 days. (Total per protocol population)

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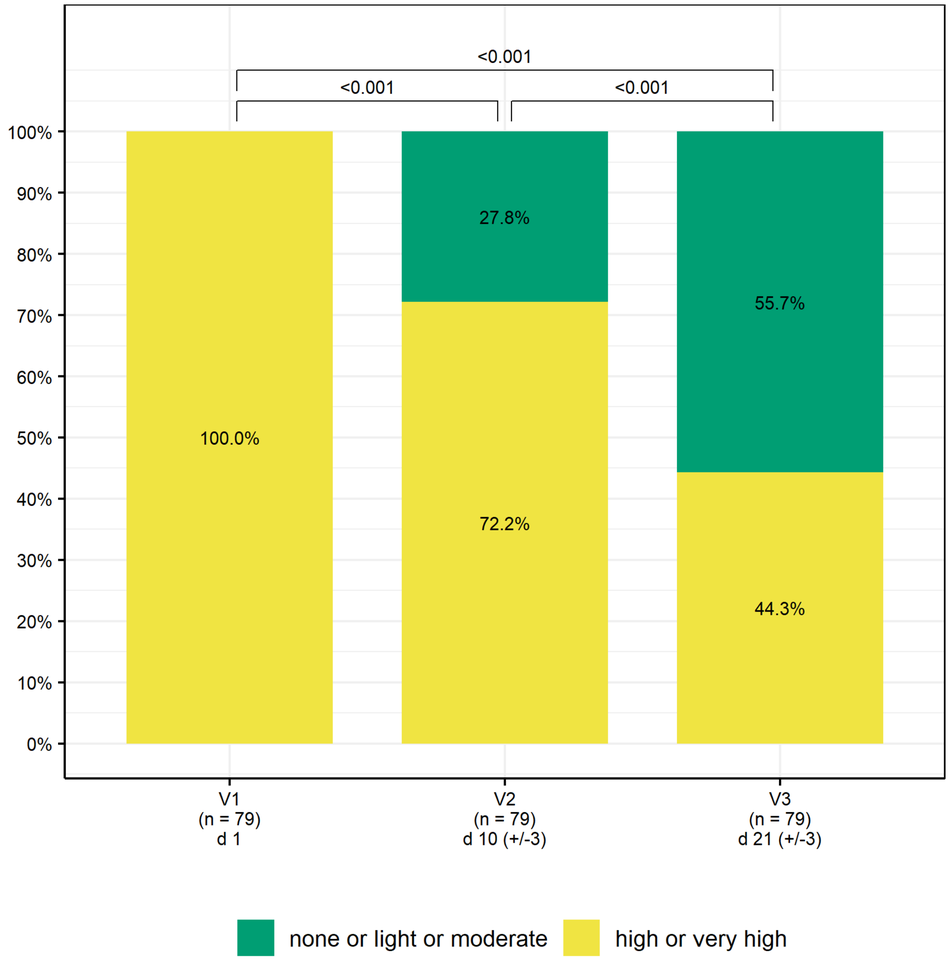
RESULTS:

In correspondence to the reduction of infected wounds, **signs of infection** (grade of exudate, pain) **reduced significantly** in both groups and quality of life improved.

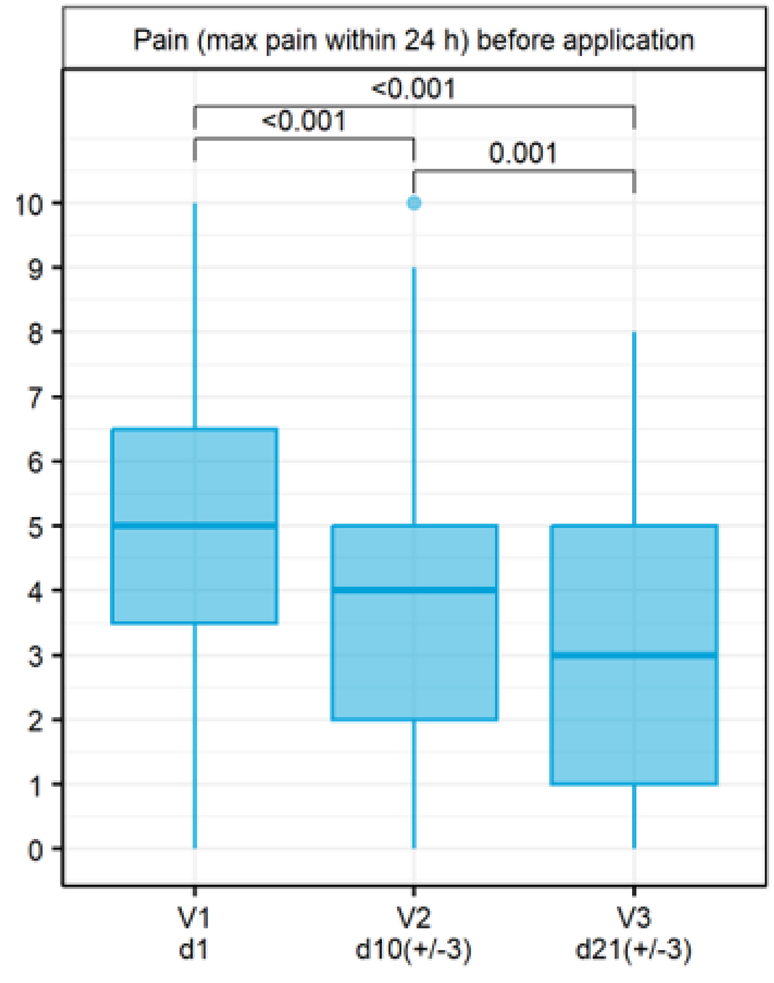
CONCLUSION:

The silver alginate[1] proved to be a **safe and effective** product for the treatment of infected wounds and wounds at risk of infection in routine clinical practice . The rapid ion release of the silver alginate leads to a **very fast onset within the first 10 days of treatment**. Secondary parameters showed a reduction of the signs of infection for infected wounds. Generally, the wounds started the healing process.



GRAPH 4: Exudate

Exudate levels changed from 100% “high or very high” (d0) to 55.7% “none, light or moderate” (d21±3). (Total per protocol population)



GRAPH 5: Pain

Median pain before application significantly decreased from 5.0 at d0 to 3.0 at d21±3 (scale 0-10). (Total per protocol population)

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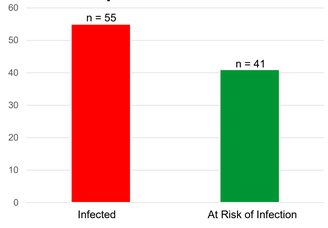

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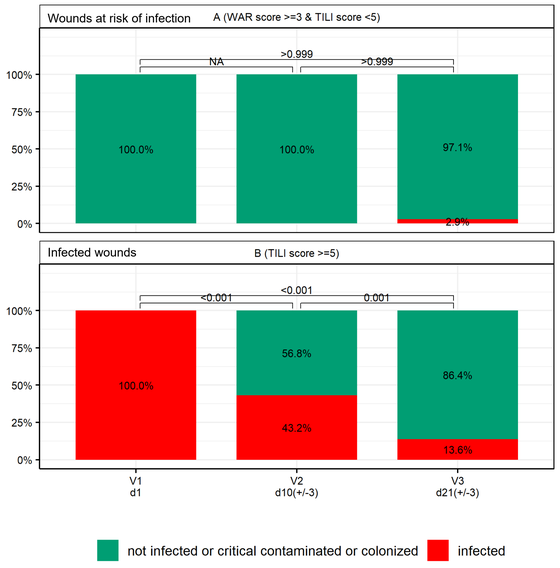
The number of infected wounds significantly decreased. Corresponding to this, a wound shift was visible with a significant increase of granulated tissue and a significant decrease of necrotic and fibrinous tissue. Moreover, signs of infection (grade of exudate, pain) reduced significantly in both groups and quality of life improved. Statistically significant onset was already visible after 10 days of treatment. Regarding safety aspects, no device deficiencies or adverse events with a clear relationship to the study procedure or study product were reported.



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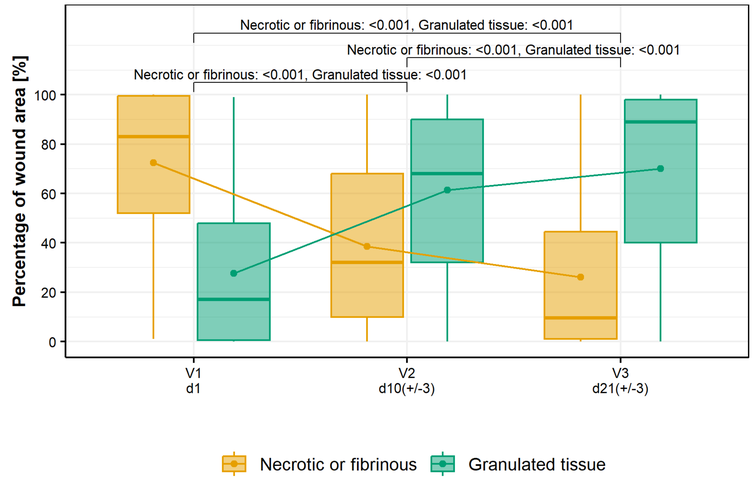

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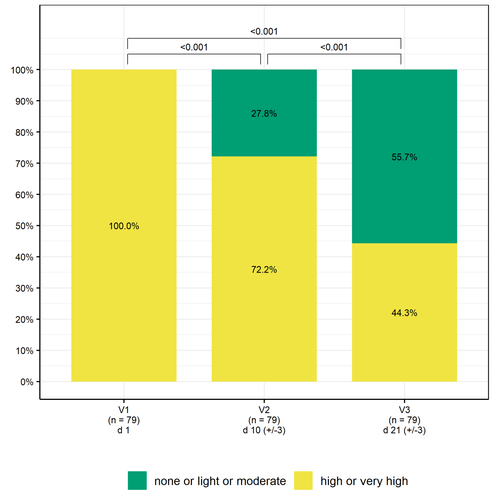

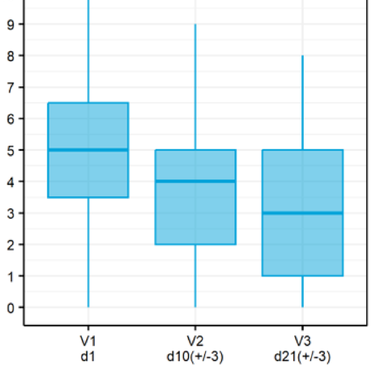

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