# Observational, multicentre, single-arm study to assess the performance, safety and handling of new antimicrobial calcium alginate dressing

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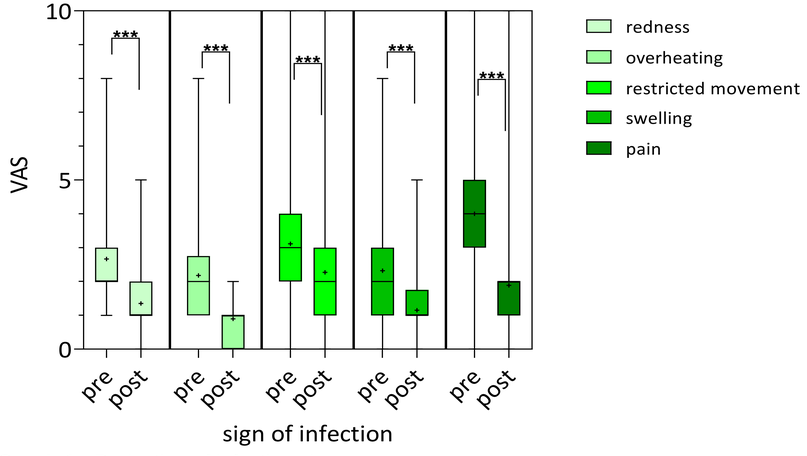
## Introduction

Wound care becomes challenging when dealing with infected or infection-prone wounds, demanding both effective infection control and proper management of wound exudate. [1] To address these challenges, a novel antimicrobial calcium alginate dressing* was developed. The objective of this study was to evaluate the dressing's performance, safety, and ease of use in the treatment of such wounds.

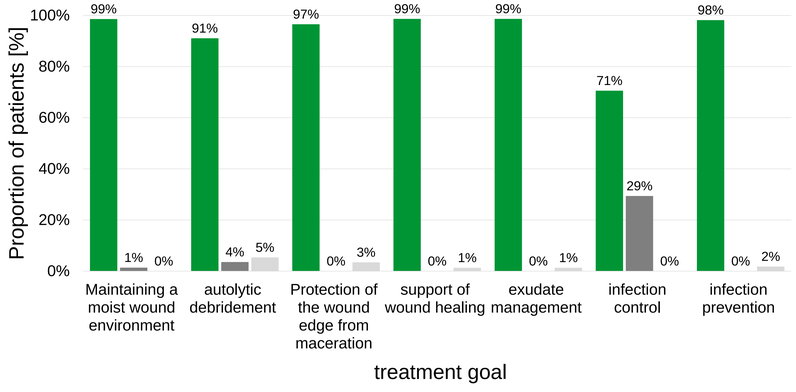
## Method

The clinical study was conducted across 5 centres in Germany. Wound managers treated 91 patients (46% male/54% female) with the investigated product, following instructions for a minimum of 4 dressing changes over a 7 to 28-day period. Data was collected using an electronic questionnaire, and the patients had an average age of 69.46 ± 16.38 years. The study followed the principles of the Declaration of Helsinki and adhered to §3 clause 4 of the German Medical Devices Act (MPDG) and §47 Section 3 of the MPDG.



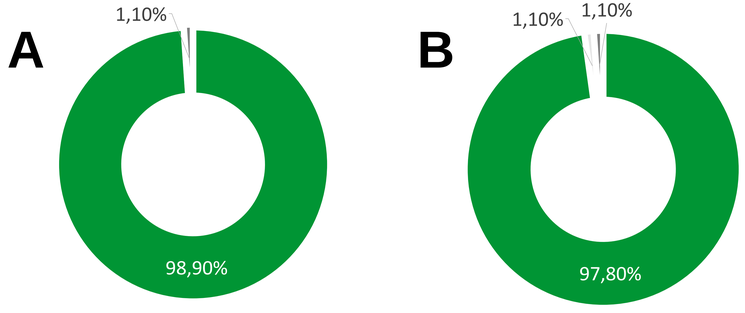

**Graph 1:** Reduction of infection signs

Box-and-whisker plot illustrating the reduction in infection signs throughout the study period. The values before the start of the study (pre) and after the completion of the study (post) are presented. Mean values are denoted by '+'. The whiskers on the graph represent the highest and lowest values reported on the Visual Analog Scale (VAS). The observed reductions are statistically significant ($p > 0.001$).




**Graph 2:** Fulfillment of treatment goals

Proportion of patients for whom the treatment goals, as set by the user, were fully achieved ( ■ ), partially achieved ( ■ ) and not achieved ( ■ ) using the calcium alginate dressing.




**Graph 3A:** Wound coverage

Proportion of patients in whom the wound remained fully covered after the dressing gelled ( ■ ), and those in whom complete coverage was no longer maintained ( ■ ).

**Graph 3B:** Prevention of maceration

Proportion of patients without maceration ( ■ ), with maceration caused by the secondary dressing ( ■ ) and attributed to the calcium alginate dressing ( ■ ) during the study period.

## Results

The study included patients with various medical conditions, such as venous leg ulcers (23.08%), postoperative wounds (23.08%), pressure injuries (20.88%), diabetic ulcers (10.99%), arterial ulcer (10.99%), and skin graft or donor sites (10.99%). Among these wounds, 42% were deep, and 58% were superficial. During the study period, indicators of infection such as redness, overheating, tissue dysfunction, swelling, and pain were significantly reduced by an average of 1.34 on the Visual Analog Scale (VAS) [Graph 1]. On average, practitioners effectively met their treatment objectives, which encompassed maintaining wound moisture, facilitating autolytic debridement, protection of the wound edge against maceration, supporting wound healing, managing exudate, controlling existing infections, preventing new infections, and stopping bleeding. These objectives were achieved at a 94% success rate with the use of the examined wound dressing [Graph 2]. In only 7.7% of cases did the wound dressing fail to gel. In 98.9% of cases, the wound remained fully covered after the dressing had gelled [Graph 3A]. The gelled wound dressing effectively removed cellular debris from the wound if present in 97.01% of cases. The dressing conformed to the wound in 98.9% of instances. Maceration resulted from the dressing in only 1.1% of cases [Graph 3B]. Wound exudate was effectively channelled into the secondary dressing in 97.2% of all cases. In 97.8% of cases, the dressing could be removed in one piece. Easily removable fibre residues were observed in 10.99% of cases. Adherence of the dressing to the wound bed occurred only in 4.4% of cases. Dressing changes were atraumatic in 97.8% of cases. The ease of use, as well as cutting the dressing when dry, was rated as very easy or easy in 100% of cases.

## Discussion

The study has shown that the tested wound dressing offers valuable assistance to healthcare professionals in the treatment of infected or infection-prone wounds. Existing infections were either reduced significantly or completely eradicated. The dressing also effectively managed wound exudate and safeguarded wound edges from maceration. Furthermore, the dressing's ability to stay intact during gentle dressing changes contributed positively to the wound healing process.

## Conclusion

This study revealed the excellent suitability of the new wound dressing for managing infected or infection-prone wounds. It offers practical insights into how the product performs in real-life situations. To obtain a more comprehensive understanding of the product's capabilities, further prospective randomized studies are required.

For more information on the product being tested, visit the L&R publication database.

References

[1] International Wound Infection Institute (2022) 'Wound Infection In Clinical Practice: Principles of best practice', Wounds International.

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