An interanal analysis of clinical investigation to evaluate exudate management and comfort of use of an antimicrobial gelling fiber dressing* in medium to highly exudative wounds

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Introduction
Wound exudate is an essential component of normal wound healing, but colonized and infected wounds, with excessive exudate and inflammation, pose a significant problem for healthcare systems worldwide.† Excessive exudate hinders wound healing, and results in leakage, soiling, odor, and pain.‡ Therefore, research into innovative exudate solutions is warranted.

Exufiber® Ag+ (Mölnlycke Healthcare, Gothenburg, Sweden) is a gelifying fiber dressing with Hydrolock™ technology (Figure 1), developed for wounds at risk of infection, or with excessive exudate where an antimicrobial dressing is indicated. Exufiber Ag+ contains silver sulphate that is evenly distributed in the dressing. Contact with wound fluid initiates a rapid and sustained antimicrobial effect against wound relevant pathogens. It has a high retention capacity to prevent leakage and maceration and the ability to absorb and retain exudate, blood and bacteria. Its high tensile strength enables dressing removal in one piece.§

Methods
This was a prospective, multi-center clinical study involving adult patients with medium to high exudative wounds, recruited between August 2017 and February 2018, who had provided informed consent. Dressing changes were performed weekly (or more often if required). Each individual was evaluated during five visits, with a total treatment period of 4 weeks or shorter if the wound was dry or healed.

Primary outcome variables
These were based on evaluations of the dressing by the nursing staff and/or investigators:
- Wound status (area, slough, granulation)/peri-wound skin
- Handling and technical performance
- Use of compression therapy
- Cleansing and debridement
- Frequency of dressing change (including due to leakage)
- Patient evaluation (comfort, conformity, acceptability)
- Adverse events (AEs)

Secondary outcome variables
These were based on our data on wound status and peri-wound skin

Results
We present interim study results. Seven study sites were involved, enrolling a total of 54 patients with: venous leg ulcers (n=24, 44.4%), diabetic foot ulcers (n=17, 31.5%) and other ulcer types (n=13, 24.1%). Three patients had one or more signs of local infection during the study (Visits 1-3) but no infection was present by Visit 4.

Most wounds were considered ‘wet’ at Visits 1 (baseline), 2, 3 and 4. By the final visit (Visit 5), the number of wounds described as ‘wet’ had significantly decreased in exudate from Visit 1 to Visit 5 in 31.4% of wounds (p=0.027), (Table 1, Figure 1). Overall, 84.2% of wounds were classified as clinically ‘improved’ and 7.9% of wounds healed. Very few wounds were recorded as ‘leaking’ during the investigation (n=7, 13.7%) requiring a dressing change.

Aims
This study had several aims in relation to performance of the Exufiber Ag+ dressing:
- Investigate its effects on wound status and peri-wound skin
- Evaluate its comfort of use in patients
- Monitor safety and tolerability

Conclusion
Exufiber Ag+ is well-tolerated and performed well in terms of exudate handling, technical performance and patient experience. Further analysis of these data is ongoing.

Conclusion
Redness/irritation and maceration, under and outside the primary dressing, improved during the study. One wound (1.9%) was recorded as having ‘distinctive malodor or change in odor’ during the study period (at Visit 3). There was a statistically significant increase in the percentage of epithelialization and a decrease in the percentage of sloughy tissue from Visit 1 to Visit 5. There was an overall reduction in the percentage of granulation tissue, reflecting epithelialization, from Visit 1 to Visit 5 (NS), and an overall increase in the percentage of necrotic tissue (from 3.3% to 14.6%), although not statistically significant, from Visit 1 to Visit 5 for those patients (n=33 at Visit 5) with chronic wounds (NS).

References
4. www.molnlycke.co.uk/advanced products/alginates

Figure 1. Exufiber Ag+ is a sterile, non-woven dressing made from highly absorbent polyvinyl alcohol fibers. In contact with wound exudate, the dressing transforms into a gel that facilitates moist wound healing.

Figure 2. Change in exudate levels between first and subsequent visits (Intention to treat population).

Figure 3. Dressing attributes judged as ‘good’ or ‘very good’ by patients.