An open, non-comparative, post-market clinical follow-up investigation to confirm performance and safety of Exufiber® when used as intended on donor sites

Mölnlycke Health Care, Gothenburg, Sweden, 2023

KEY POINTS

- Split-thickness skin graft (STSG) **donor sites** are associated with numerous challenges, such as high exudate levels, risk of complications (e.g. haematoma, infection), patient pain and cosmetic inconveniences.
- In a clinical study involving 33 patients, the efficacy and safety of **Exufiber®** (gelling fibre dressing) in the management of donor sites was evaluated.
- Analysis revealed high healing rates: **60.6% of donor sites had healed within 2 weeks; 75.8% within 3 weeks.** [Mean length of treatment with Exufiber® was 14.5 days.]

INTRODUCTION

- Autografting with split-thickness skin grafts (STSGs) is an essential procedure in burn and reconstructive surgery. The process of harvesting a STSG leaves behind a **donor site**, an exposed area of partial-thickness dermis left to heal by secondary intention.
- The ideal donor site dressing allows for speedy and efficient healing while minimising pain and risk of complications. It should also have a long wear time, thus allowing the wound to remain undisturbed.

METHODOLOGY

- Adult patients undergoing STSG transplantation with donor sites on the thigh were recruited.
- **Exufiber®** was applied directly to the donor sites. **Mepilex®** (soft-silicone-coated, non-bordered foam dressing) was used as a secondary dressing. If required, a fixation device (tape and/or bandage) was also applied. If, according to the investigators' judgement, Exufiber® was no longer deemed necessary, then Mepilex® was used as the primary dressing.
- Follow-ups were scheduled for days 3 and 14, and day 21 for patients with donor sites that had not healed.

Key outcome measures	
Primary	Wound progress of the donor site from baseline (day 1) to the last visit when Exufiber® was used, up to day 21
Secondary	Clinicians' evaluation of usability and properties of Exufiber® including **dressing wear time** Patients' evaluation of pain severity
Safety	Occurrence of device-related adverse events

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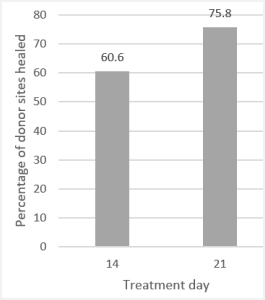
RESULTS

- **Patient population**. Data from 33 patients were analysed.

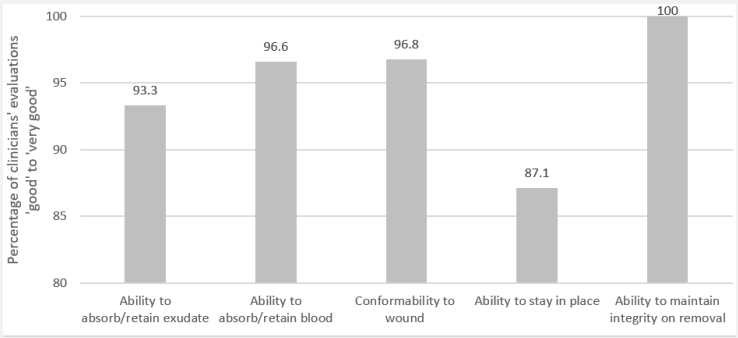
Primary outcome



- 20/33 (60.6%) of patients were judged as healed at day 14.
- 25/33 (75.8%) of patients were judged as healed within the 21 days of follow-up.
- Mean length of treatment with Exufiber® was 14.5 days.

Secondary outcomes

Clinicians' evaluations



- High percentage of 'good' to 'very good' clinicians' ratings for the ability of the dressing to absorb/retain exudate (93.3%), absorb/retain blood (96.6%), conform to the wound bed (96.8%) and maintain integrity when wet on removal (100%).
- Clinicians reported no dressing remnants in the wound bed in 84% of evaluations.
- Mean wear time per individual dressing was 12.2 days (≥14 days in 61.5% of patients).

Patients' evaluations

- High percentage of 'good' to 'very good' patients' ratings for comfort during wear (93.9%) and experience during dressing changes (86.6%).
- Mean pain score recorded at Exufiber® dressing removal was 1.3, on a scale from 0 = no pain to 10 = worst pain imaginable). 22 (66.7%) patients reported no pain.

Safety outcomes

- Only 4 adverse device events reported: donor site trauma on dressing removal (n=2); suspected infection (n=2).

CONCLUSIONS

- The results of this study are a good indicator of the suitability of Exufiber® for donor site management.
- The dressing was associated with good donor site progression and was rated highly by both clinicians and patients.

This summary has been compiled by the Global Medical Affairs Department of Mölnlycke Health Care as a service to healthcare professionals. It does not contain the complete text and Mölnlycke Health Care makes no representation as to its completeness in addressing all issues in the item to which it refers.

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