A post market follow up study to demonstrate the safety and efficacy of a gelling fibre product (Exufiber, Mölnlycke Health Care Sweden) for the management of donor sites.

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Objectives

This investigation was a prospective, open, non-comparative, PMCF investigation to confirm performance and safety of Exufiber when used as intended on donor sites. The investigation included eligible subjects undergoing split-thickness skin grafting. The location where the skin is harvested from, i.e. donor site, was treated with the investigational device, Exufiber, as primary dressing and a standardized procedure of Mepilex as secondary dressing, followed by a third dressing (tape and/or bandage) as required.

Methods

38 eligible subjects were included in a single centre in Sweden. All subjects were followed up for a period of at least 14 days. Follow ups were performed at day 3, day 14, and for those patients who were not yet healed at a final visit at day 21.

In total 38 subjects were screened and 33 were available for analysis.

The reasons for need of split skin graft transplantations were cancer or tumor related (51.5%), burn (12.1%) or other (36.4%). Other reasons for grafting given in free text were leg ulcer (n=4), fistula in mouth, Fournier's gangrene, hidradenitis suppurativa, atypical wound, post operative defects, surgery reconstruction of a defect after a hemi maxillectomy, traumatic wound and post deep dissecting hematoma wound.

Results

29 donor site wounds (87.9%) improved, 2 wounds remained unchanged (6.1%), and 2 wounds were assessed as deteriorated (6.1%).

Exufiber was used up to 21 days. At day 14, 20 donor sites out of 33 had completely healed. Of 13 donor sites assessed as not completely healed at day 14, a further 8 had improved healing outcomes after Exufiber was discontinued and next follow up visit at day 21.

The average wear time for Exufiber was 12.2 days with only 4 patients requiring dressing changes before the 14 day follow up. The majority of patients no longer required Exufiber due to healing or because the wound had progressed significantly with low exudate levels.

•For most subjects, the clinician evaluations of Exufiber were assessed as 'Good' or 'Very good' on ability to absorb exudate (93.3%), ability to retain exudate (93.3%), ability to absorb blood (96.7%) and ability to retain blood (96.7%). A total of 17.2% of subjects were assessed as having any exudate leakage and 17.6% of subjects were assessed as having any blood leakage.

•In total there were 29 adverse events, only 4 related to the dressing.

The majority of which related to surgical wound complications and the patient's co-morbidities. 2 patients had site trauma upon removal.

•Donor site infection was suspected in 2 patients and confirmed in 1 patient.

Case Study

This 63 year old male patient had a skin graft due to Fournier's gangrene in the perineal area.

The donor site was 15cm x 15cm.

The wound bled initially and Exufiber managed the serosanguineous exudate. Mepilex was used as the secondary dressing. Image 1 shows blood staining on the Exufiber dressing on day 14. Image 2 shows the same wound with the dressing removed. Complete healing has been achieved.

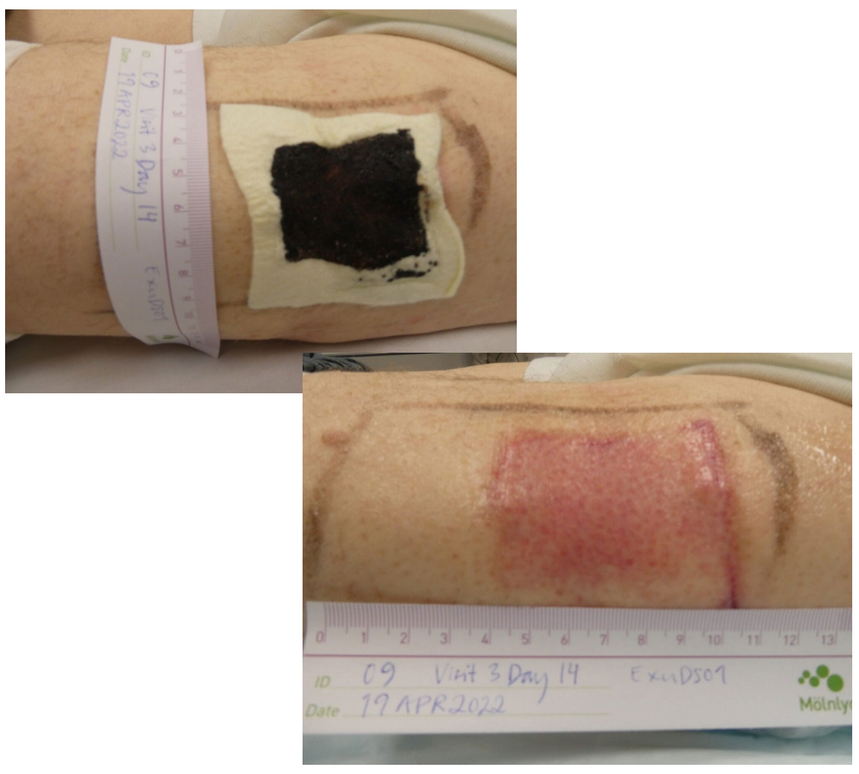

Image 1 shows Exufiber in situ at day 14,
Image 2 is following removal of the dressing.

Conclusion

This non comparative study demonstrated that the gelling fibre dressing was able to manage donor sites safely and efficiently. The gelling fibre product was able to absorb haemoserous exudate and transfer into the secondary dressing. The majority of patients' donor sites healed without complication, the dressing also stayed in place and all the clinicians rated the product good or very good for one piece removal.