An open, parallel, randomized, comparative, multicenter investigation evaluating the efficacy and tolerability of Mepilex® Ag vs silver sulfadiazine in the treatment of deep partial-thickness burn injuries

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Aim

To determine the efficacy and tolerability of silver sulfadiazine (SSD) compared with an absorbent foam silver dressing, Mepilex® Ag.

Method

Prospective, randomized controlled trial

Deep partial-thickness thermal burns patients who met the inclusion criteria (2,5-25% TBSA, patients between 5 and 65 years) were randomized to one of two intervention groups:

1. Mepilex® Ag
2. Silver sulfadiazine cream (SSD)

Results

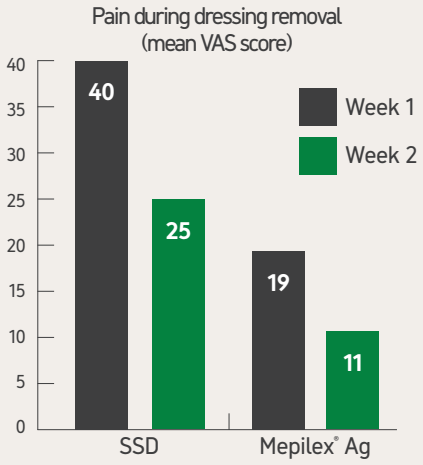
Healing time

There was no statistical difference between the two groups with regard to burn healing.

Pain

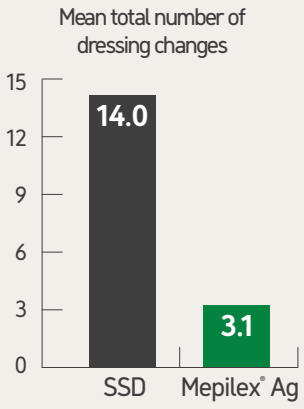
Before burn assessment, there was no significant difference in experience of pain between the 2 groups.

At weeks 1 and 2, pain at dressing change was significantly lower in the Mepilex® Ag group before, during and after dressing removal compared with the SSD group.



Number of dressing changes

The number of dressing changes was significantly lower for Mepilex® Ag compared with SSD.



Experience of use

Clinician

Mepilex® Ag was found to be significantly easier to apply and remove compared with SSD (p<0.0001).

Patient

Patients evaluations of 'experience of anxiety during dressing change', 'ease of movement while wearing the dressing' and 'stinging or burning while wearing the dressing' significantly favored Mepilex® Ag compared with SSD (p<0.0001).

There was no difference in healing time between Mepilex® Ag and SSD, with both products well tolerated. The longer wear time of Mepilex® Ag promotes undisturbed healing and makes it easier for patients to continue with their normal lives sooner.

More about the study

Outcomes measured

Primary outcome measures

- Time to healing (≥95% epithelialisation by visual inspection)

Secondary outcome measures

- Percentage of burns epithelialised/healed
- Number of burns healed or not at each visit (not at baseline)
- Number of study burns requiring a skin graft
- Number of dressing changes
- Outcomes to assess tolerability and performance of the dressings on wound and periwound status (pain using the VAS-scale and experience of use)

Additional results

- 158 patients were randomized and 153 patients were included in the ITT population (subjected to at least one treatment):
  - Mepilex® Ag (n=71)
  - SSD (n=82)

Healing outcomes:

- At visit 2 (week 1), the **number of study burns healed** was **significantly greater in the Mepilex® Ag group** compared with the SSD group (respectively 13 and 4; p=0.016).
- At visit 2, the **percentage of study burns healed** was **significantly greater in the Mepilex® Ag group** compared with the SSD group (mean, 44.3% and 27.0% respectively; p=0.0092).

Pain

Visit	Variable	Mepilex® Ag	SSD	P
Visit 1 (day 0)				
	Pain before burn assessment	35.3 (22.4), 35.0 (0.0–96.0), n=70	42.9 (25.8), 40.3 (0.0–100.0), n=76	0.0712
Visit 2 (week 1)				
	Pain before dressing removal	11.7 (14.4), 6.0 (0.0–80.5), n=64	23.9 (21.4), 19.5 (0.0–92.0), n=75	<0.0001
	Pain during dressing removal	19.4 (17.8), 18.3 (0.0–88.5), n=64	40.1 (24.6), 39.0 (0.0–94.0), n=75	<0.0001
	Pain after dressing removal	17.3 (20.1), 10.0 (0.0–87.5), n=64	34.3 (24.1), 31.0 (0.0–88.0), n=75	<0.0001
Visit 3 (week 2)				
	Pain before dressing removal	6.99 (11.49), 1.88 (0.0–64.0), n=64	14.9 (17.3), 8.5 (0.0–73.0), n=75	0.0002
	Pain during dressing removal	10.8 (13.4), 5.0 (0.0–67.0), n=64	24.7 (23.8), 18.1 (0.0–92.0), n=75	0.0003
	Pain after dressing removal	9.34 (15.74), 3.00 (0.0–79.60), n=64	21.2 (20.1), 16.0 (0.0–84.0), n=75	<0.0001

For continuous variables, mean (SD), median (minimum-maximum), and n is presented
For comparison between groups, the Mann-Whitney U-test was used for continuous variables.
LOCF is used for missing values. Baseline values are not carried forward.

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