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

Tang H et al. Journal of Trauma and Acute Care Surgery. 2015;78(5); 1000-1007.

Aim

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

Method

Prospective, randomised controlled trial

Deep partial-thickness thermal burns patients who met the inclusion criteria (2.5-25% TBSA, patients between 5 and 65 years) were randomised to one of two intervention groups:

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

Results

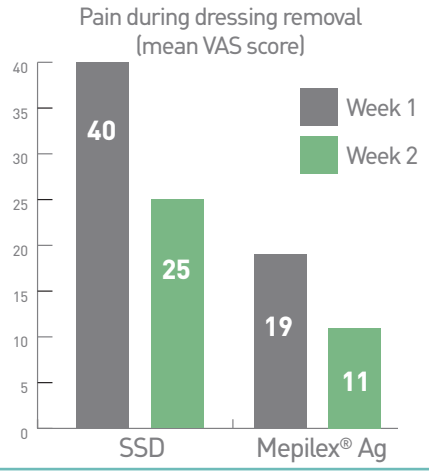
Healing time

Mean healing rates were 71.7% Mepilex Ag group vs 60.8% Silver sulfadiasine group at the final visit. This was not a statistically significant difference.

Pain

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

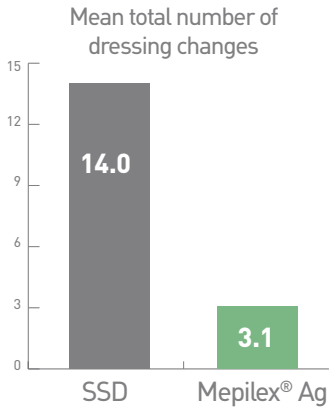
At weeks 1 and 2, pain at dressing change was significantly lower in the Mepilex® Ag group before, during and after dressing removal compared with the SSD group.



Number of dressing changes

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

The average cost-effectiveness per treatment was $381 lower in the Mepilex Ag group.



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.

Additional useful information

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 randomised and 153 patients were included in the * 158 patients and * completing (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)		SD	SD	
	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.