Assessment of local tolerability and wound healing properties of first aid dressings in sensitive, mature skin and diabetics in a suction blister wound model

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Abstract

Objective: The objective of the study was the assessment of the local tolerability and efficacy of first aid dressings to be used in volunteers with sensitive skin in comparison to untreated wounds in a suction blister wound model.

Method: Thirty-two healthy volunteers (> 60 years) with sensitive skin, including 11 diabetics, were enrolled into a monocentric, investigator-blind, randomized clinical study. Four standardized, superficial wounds were induced on the inner sites of the volar forearms of each volunteer using the suction blister wound model. Three different medical devices intended to be used in sensitive skin and gauze serving as control were randomly allocated to the test areas. On study days 2, 4 and 9 ± 1, the investigator determined wound healing and local tolerability parameters. Additionally, an overall assessment of local tolerability, efficacy and product traits was carried out by volunteers and dermatologists.

Results: Local tolerability of all test products was confirmed by dermatological assessment. The wound healing efficacy of test products was superior compared to the untreated control area (gauze) with significant increases in reepithelization and significantly lower eschar formation. Also, overall assessment of efficacy confirmed the data with best results seen for the product with integrated healing cream followed by the product with silver technology. Photo documentation supports the findings. No adverse events were reported. Volunteers perceived significant benefits from the test products regarding product traits and overall assessment of local tolerability. Erythema at the plaster adhesion sites were observed compared to the control area. All test products were confirmed by dermatologists using a 7-tiered score from fully disagree (score 1) to fully agree (score 7). Volunteers were also asked to rank product traits. Photo documentation was used to further evaluate results. Any adverse events were documented and analyzed.

Conclusion: The local tolerability and wound healing efficacy of the first aid dressings and their suitability to be used in persons with mature, sensitive skin, including 11 diabetics, was confirmed by dermatologist and volunteers. All test products were superior to the untreated control (gauze) regarding overall wound healing efficacy and confirmed the local tolerability of all test products.

Discussion and Conclusion

The objective of this monocentric, investigator-blind, randomized, intra-individual clinical study was to investigate the local tolerability and wound healing efficacy of first aid dressings in volunteers with mature, sensitive skin in comparison to untreated wounds in a suction blister wound model.

Methods

Three different medical devices intended for the treatment of small, superficial everyday wounds all of them to be used in sensitive skin were tested:

- a standard non-sterile, air- and water-permeable first aid dressing (Hansaplast® Sensitive)
- a dressing with an integrated healing cream providing a protective barrier and creating moist wound healing conditions (Hansaplast® Sensitive plus Healing Cream)
- a dressing with a wound pad containing a silver coated polyethylene net providing an antimicrobial effect (Hansaplast® Sensitive with Silver Technology).

Evaluation of wound healing: Reepithelization determined by the investigator by visual assessment (Figure 1). A significantly lower eschar formation was determined for all test products compared to the untreated control on study days 2, 4 and 9 (Figure 2). Video microscope images (Figure 3, shown exemplary for one volunteer) support these findings.

Overall assessment of the dermatologist and volunteers/patients, product traits: Evaluation of overall local tolerability and assessment of efficacy were determined on study day 9. Results from volunteer and dermatologist questionnaires significantly confirmed over-all local tolerability and wound healing efficacy of all three test products (Figures 4 and 5). Best results were obtained for the product with integrated healing cream followed by the product with silver technology. Volunteers perceived significant benefits from the test products with respect to product traits such as removal, edema and redness at the plaster adhesion sites as determined by the investigator by visual assessment.

Conclusions: The local tolerability and wound healing efficacy of the first aid dressings were superior compared to the untreated control area (gauze) with significant increases in reepithelization and significantly lower eschar formation. The determined differences between products were small.