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

Aim: 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 wound healing efficacy and confirmed the local tolerability of all test products.

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 with best results for the product with integrated wound healing cream.

Introduction

The occurrence of superficial, acute wounds is common in everyday life. To protect wounds from external influences during the healing process, wound dressings are used. The objective of this study was the dermatological assessment of the local tolerability and efficacy of first aid dressings to be used in volunteers with sensitive, mature and/or diabetic skin in comparison to untreated wounds. For an intra-individual comparison of minor artificial wounds the suction blister wound model was used. With this noninvasive technique standardized defects are created and epithelial regeneration can be studied. Defects heal scar-free.

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 antiseptic effect (Hansaplast® Sensitive with Silver Technology).

Patients and Methods

Volunteers: 32 volunteers (24 female, 8 male, > 60 years) with sensitive skin were enrolled and finished the study. Eleven volunteers were type II diabetics and under medical treatment. All volunteers were included according to the in- and exclusion criteria and signed a written declaration of consent.

Induction of suction blister wounds: After a one week preconditioning period, four standardized, superficial wounds (6 mm in diameter) were induced on the inner sites of the volar forearms (2 test sites per forearm) of each volunteer using the suction blister wound model as described before.

Test Products/Product Application: Three different medical devices* and gauze as control were randomly allocated to the four test areas. The study was conducted investigator-blind. All three test products were marketed CE-certified medical devices.

Test Protocol: On study days 2, 4 and 9 ± 1, local tolerability was determined by visual assessment of edema and redness at the plaster adhesion sites as well as rubor, tumor, secretion of sanies, dolor and calor at the wound pad site by the dermatologist using a 5-tiered score (0 = no, 1 = initiating, 2 = about half, 3 = nearly complete, 4 = complete) or a yes/no scale, respectively. On the same days, reepithelization was determined by visual assessment utilizing a 5-tiered score (0 = no, 1 = initiating, 2 = about half, 3 = nearly complete, 4 = complete) and eschar formation using a 4-tiered score (0 = no, 1 = slight, 2 = moderate, 3 = strong). On day 9, a questionnaire for overall assessment of local tolerability and wound healing efficacy was completed by volunteers and 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.

Results

Local tolerability: The local tolerability of all three test products was confirmed by the dermatologist. Assessment of local tolerability did not yield any signs of edema, secretion of sanies, dolor (only 1 patient) or calor at the wound pad site. No signs of edema were observed at the plaster adhesion site. Volunteers displayed only little, in general inconspicuous signs of erythema at the wound pad sites (mean values of erythema scores at the wound pad sites were below 0.5) and the plaster adhesion sites. The determined differences between products were small.

Wound healing: Already on study day 4, results demonstrated a significant increase in reepithelization for the plaster with integrated healing cream and the product with silver technology compared to the untreated control (gauze). On day 9, treatment with all three test products showed a significant increase in re-epithelization scores compared to the untreated control (Figure 1).

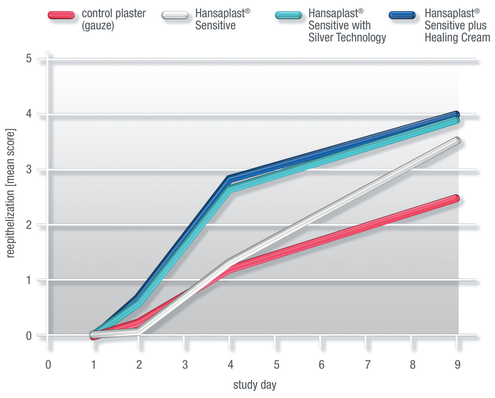

Figure 1: Evaluation of wound healing: Reepithelization determined by the investigator by visual assessment.

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 exemplarily for one volunteer) support these findings.

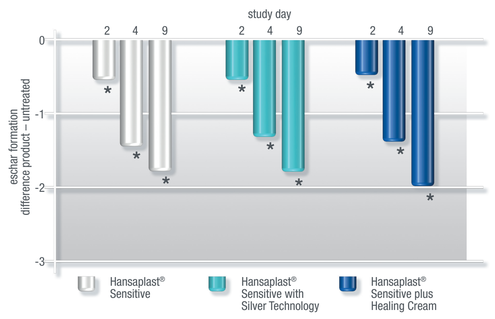

Figure 2: Evaluation of wound healing: Decrease in eschar formation. Shown is the difference product – untreated. Significant differences are marked with an asterisk (* for p ≤ 0.05).

Overall assessment by the dermatologist and volunteers/patients, product traits: Evaluation of overall tolerability and assessment of efficacy were determined on study day 9. Results from volunteer and dermatologist questionnaires significantly confirmed overall 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, material properties and handling.

Safety: During the course of the study, neither serious side effects nor non-serious adverse effects were reported.

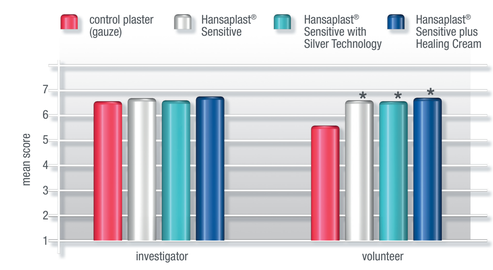

Figure 4: Overall tolerability of test products as determined by the dermatologist and volunteers. Results are shown as mean score. Significant differences product – untreated are marked with an asterisk (* for p ≤ 0.05).

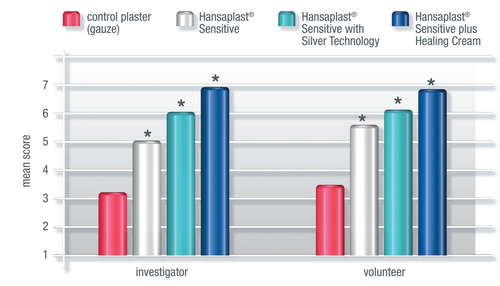

Figure 5: Overall wound healing efficacy of test products as determined by the dermatologist and volunteers. Results are shown as mean score. Significant differences product – untreated are marked with an asterisk (* for p ≤ 0.05).

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.

Dermatological assessment confirmed the local tolerability of all test products. Significant increases in re-epithelization and significantly lower eschar formation were observed compared to the control area. All test products were superior to the untreated control regarding overall local tolerability and overall wound healing efficacy with best results for the product with an integrated wound healing cream supporting moist wound healing properties. With respect to the investigated parameters the diabetics did not show noticeable deviation from the pool of volunteers. Regarding product safety no negative aspects were documented in this study.

In summary, the local tolerability and wound healing efficacy of the first aid dressings and their suitability to be used in persons with challenging skin conditions, including 11 diabetics, was confirmed by dermatologist and volunteers.

Day 4

Day 9

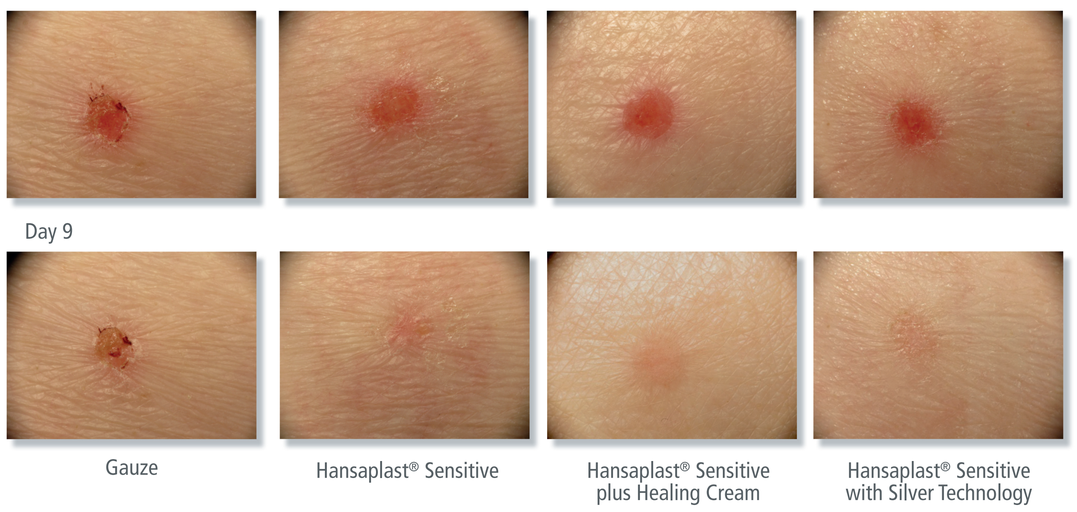

Figure 3: Video microscope images (shown exemplarily for one volunteer) of wound response on days 4 and 9.

References are available on request.

* Reference: Hansaplast® Sensitive, Hansaplast® Sensitive plus Healing Cream, Hansaplast® Sensitive with Silver Technology.

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