Novel Abrasive Wound Model to Investigate the Healing Properties of Different Dressings for Superficial Wounds

An Open-Label, Randomized, Intra-Individual Clinical Study

Wigger-Alberti W, MD[1], Ekanayake S, MD[1], Wilhelm D, MD[1], Kuhlmann M, MD[2], Buettner H. PhD[2], Callaghan T, PhD[1], and Wilhelm KP, MD[1]

[1] proDERM Institute for Applied Dermatological Research, Schenefeld-Hamburg, Germany | [2] Beiersdorf AG, Hamburg, Germany

The products used in the clinical studies are available under the brand Hansaplast as well as Elastoplast depending on the respective country in which the brand is available.

Abstract

Aim: The objective of the study was the assessment of the suitability of a new abrasive wound model to evaluate wound healing and make comparisons between different types of wound dressings and further to compare wound healing rate and overall cosmetic outcome of wounds treated with different medical devices intended for moist or dry wound healing of superficial everyday wounds.

Methods: A total of ten healthy volunteers were enrolled in the open-label, randomized, intra-individual comparison. On the forearms of each volunteer five standardized, superficial abrasive wounds were induced by scrubbing the skin repeatedly with a surgical brush until first signs of uniform glistening and punctuate bleeding was observed. Three dressings intended for moist wound healing (polyurethane, hydrocolloid, hydrogel) and two standard dressings were randomly allocated to the test area.

Results: Evaluation of wound healing at study days 2, 5, 8, and 14 +1 performed by investigator showed best results for wound healing for the polyurethane product and the hydrocolloid product dressing. Visible re-epithelisation could already be recorded at study day 5 and at day 8 more than 50% of the wound had be resurfaced. Video microscope images support these findings. Also cosmetic outcome assessed by investigator and panellists was evaluated best for polyurethane and hydrocolloid product with very high mean scores close to the maximum score of 10. Histological examination of biopsies taken from the abrasive wounds of two volunteers showed that the model is especially suitable for studies of these superficial wounds since the dermis remains intact.

Discussion/Conclusion: Uniform and identical standardized wounds created using an abrasive brush technique could be employed reliably to detect differences in the performance of wound dressings intended for the healing of superficial wounds. In general moist wound healing showed better results compared to dry wound healing with an earlier onset and a better outcome of healing. Superficial cutaneous wounds treated with a polyurethane or a hydrocolloid product demonstrated superior rates of repithelisation and overall cosmetic outcome.

Introduction

The occurrence and subsequent healing of small, superficial acute wounds such as cuts and abrasions is a familiar everyday process and in healthy skin, these wounds usually heal without consequences.

In the clinical setting, the investigation of any wound processes is dependant on the use of models. Small identical standardized wounds are required to perform wound healing studies in order to compare different wound treatments on an intra-individual basis. Obviously, current methods such as transepidermal water loss, sellotape stripping, suction blister or mini-incisions do not reflect the real life situation of accidentally induced superficial wounds such as abrasive wounds, and there is still need for realistic and standardized models. Abrasive models such as mechanical induction using an emery wheel for dermabrasion were considered an option yet considered too invasive. A novel model was developed using a standardized brush technique to induce uniform abrasive wounds.

Beneficial effects of occlusive and semi-occlusive wound treatment e.g. hydrocolloid, polyurethane or hydrogel dressings are well documented. They promote healing by providing a moist environment that increases not only the rate of re-epithelisation, but affects all aspects of healing. Clinical studies have shown that moist wound therapy accelerates wound healing both in partial thickness and full thickness wounds in humans.

The purpose of this study was three-fold – firstly to produce standardized identical abrasive wounds, secondly to determine if identical wounds created by this new abrasion model could be used to evaluate wound healing and make comparisons between different wound dressings, and thirdly to compare the wound healing rate and overall cosmetic outcome of wounds treated with these dressings.

Patients and Methods

Volunteers: Ten healthy volunteers (1 male, 9 female, mean age 32.8 years) were enrolled onto the study. All in- and exclusion criteria were verified before inclusion of panelists. Informed consent was obtained from all subjects and the study was approved by an independent ethics committee.

Wound Induction: In total, 5 standardized, superficial, abrasive wounds were induced on the forearms of the volunteers. A template was applied to the skin and 1.2 cm epidermal abrasive wounds were induced with a sterile surgical brush by scrubbing the skin repeatedly until first signs of uniform glistening and punctuate bleeding. No anesthetic was required for this procedure. In two panelists an additional wound was induced and a skin biopsy taken directly after induction for histological evaluation.

Test Products/Product Application: All test products were randomly allocated to the test area. The products intended for moist wound healing were a Polyurethane Dressing (Hansaplast Fast Healing) a Hydrocolloid Dressing (Hansaplast Blister Plaster) and a Hydrogel Dressing compared to a waterproof dressing and a standard air and water permeable wound dressing both providing dry wound healing conditions.

Test Protocol: Wound healing was evaluated by the investigator at study days 2, 5, 8, and 14 ±1 and additionally documented by video microscopy (No healing 0%, Resurfacing >0 up to 25%, Resurfacing >25 up to 50%, Resurfacing >50 up to 75%, Resurfacing > 75% but not complete, Complete closure of surface). Panelists judged product traits on a 7 point scale by filling-in a questionnaire. At day 31 a final follow-up examination was conducted to judge the cosmetic outcome/acceptance of the products using a visual analog scale ranging from 0 (poor) to 10 (excellent). Physical examination of volunteers focused on the skin, and any adverse events were documented and analyzed.

Results

Wound Induction Evaluation: Wounds induced with the abrasive brush method showed good uniformity (Figures 1a-c). Punctate bleeding was observed in all wounds indicating removal of the epidermis. Wound healing rate and quality was imaged over a period of 14 days.

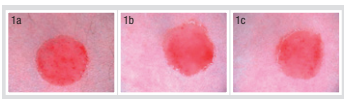

Fig. 1a-c: Standardized wound induction

Biopsy Histology Assessments: Histological examination of biopsies taken from the abrasive wounds of two volunteers showed the suitability of the model. PAS staining results of biopsies taken from the wound bed edge of fresh wounds showed that only the epidermis had been removed with no papillary dermal damage (Figure 2a) and that the glycogen-rich basal lamina remained intact (Figure 2b).

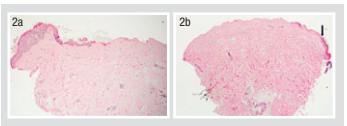

Fig. 2a-b: Abrasive wounds – histological examination of biopsies

Results Wound Healing: Evaluation of wound healing at study days 2, 5, 8, and 14 +1 performed by investigator showed best results for wound healing for the polyurethane product and the hydrocolloid product dressing (Figure 3 and 4). Visible re-epithelisation could already be recorded at study day 5 and at day 8 more than 50% of the wound had be resurfaced. Video microscope images support these findings (Figure 5).

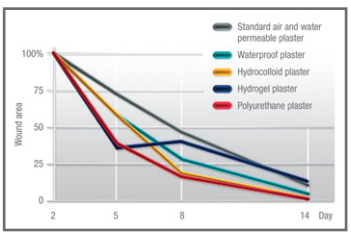

Fig. 3: Evaluation of wound healing: visible re-epithelisation at study days 2, 5, 8 and 14

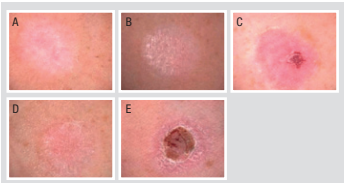

Fig. 4: Videomicroscope images of wound responses at day 14
A = Polyurethane plaster, B = Hydrocolloid plaster, C = Hydrogel plaster
D = Waterproof plaster, E = Standard air and water permeable plaster

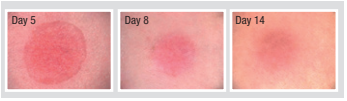

Fig. 5: Videomicroscope images – moist wound healing (polyurethane plaster)

Assessment of Cosmetic Outcome/Acceptance: Cosmetic outcome was assessed using a visual analog scale. Investigator evaluated best for the polyurethane and hydrocolloid product with very high mean scores close to the maximum score of 10. The panelists judged cosmetic outcome similar to the investigators judgment, however their mean scores were lower, yet the trend was the same (Figure 6).

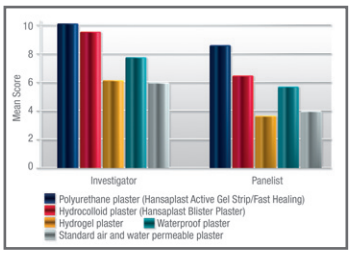

Fig. 6: Mean scores for cosmetic outcome of tested products

Determination of Product Traits: In a questionnaire the panelists determined product traits regarding: handling and adhesion; material properties/appearance; removal of products; and effectiveness. The hydrocolloid product received the highest mean scores of all products followed by the polyurethane product. The results of the "efficacy" as judged by the panelists correlated well with the wound healing assessments of the investigator.

Safety: Neither infectious nor allergic or unusually strong irritant reactions were seen at any of the superficial abrasive wounds. However, in two panelists skin reactions surrounding the wound were observed. Considering the type, number and outcome of adverse events, no negative aspects regarding safety were seen in this study.

Discussion and Conclusion

In this open-label, randomized, intra-individual comparison it could be shown that uniform and identical standardized wounds created using an abrasive brush technique could be employed reliably to detect differences in the performance of wound dressings intended for the healing of superficial wounds.

The primary purpose of this study was to produce standardized identical abrasive wounds, to reflect more closely, the clinical situation in superficial wounding. The accuracy and reproducibility of each wound induction was found to be identical, enabling standardized comparisons. In particular, the wounds can be created under identical conditions, and are of identical surface area and depth, as supported by histological examination. No anesthetic was required prior to wound induction. The wound model itself can be considered the clinical equivalent of every day abrasions and grazes. Furthermore, these wounds are adjacent to each other within the same body area, making clinical examination more comparable.

In general products intended for moist wound healing showed better results compared to dry wound healing with an earlier onset and a better outcome of healing. Superficial cutaneous wounds treated with a polyurethane or a hydrocolloid product demonstrated superior rates of repithelisation and overall cosmetic outcome.

References

Available on request.

Filed for publication