

WOUND HEALING

Efficacy and safety of a wound healing cream

This case study describes a fully ISO14155-compliant medical device project as typically conducted by proderm. The objective is to evaluate the wound healing efficacy and safety of a new wound healing product using a suction blister wound model. In 2020 and 2021, our proderm study team managed to adapt to the mounting challenges posed by the COVID 19 pandemic and successfully complete this kind of clinical investigation.

Study specifications:

- randomized
- intra-individual
- comparison treated vs. untreated
- open label
- monocentric
- 44 healthy volunteers to be randomized, including a 10% expected drop out rate
- Eight planned visits
- Wound model: Induction of suction blisters
- Twice daily application of product at home

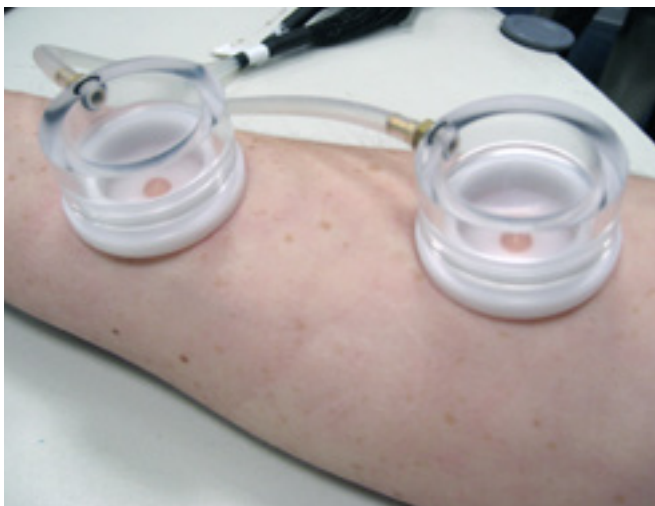


Measuring wound healing

Induction of the wound

Suction cup blisters are a wound healing model we routinely and successfully employ at proderm with great consistency inducing standardized wounds of similar shape and depth. In the hands of our highly qualified and extremely experienced study staff, this model generates highly reliable clinical data on wound healing efficacy. Suction cups are fixed on the skin and connected via tubes with a negative-pressure pump. The constant

negative pressure leads to the formation of suction blisters. The skin is separated between the epidermis and the dermis at the dermal epidermal junction. The blisters are filled with clear transparent interstitial fluid. Blister fluid as well as blister roof are carefully removed and can be sampled. Usually a formation of scars is not anticipated when applying this method.



Suction process



Raised blister



Fluid extraction



Blister roof removal



Inflicted wound

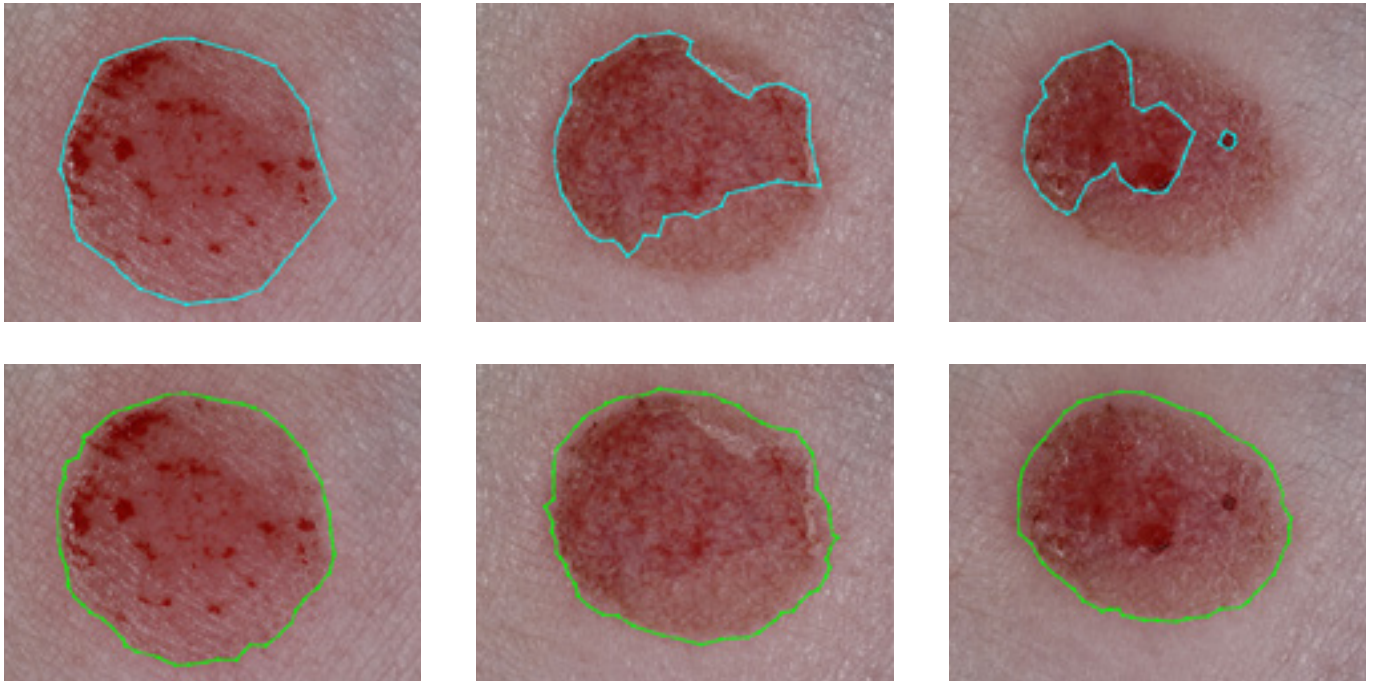


Objective of the study

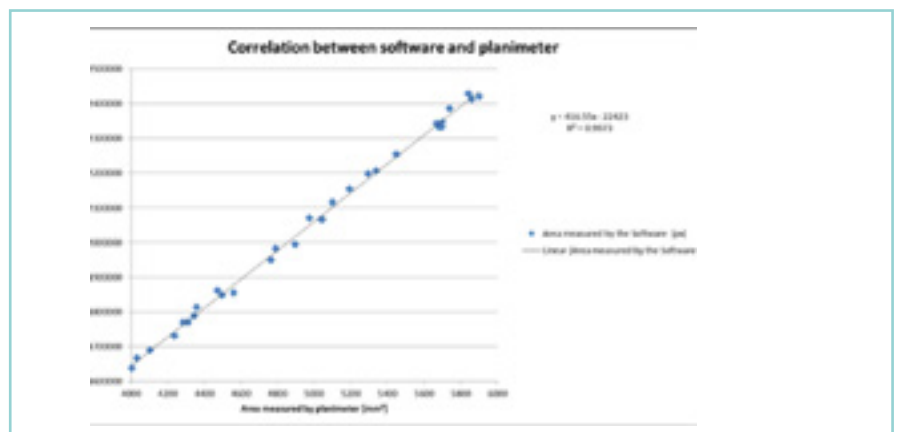
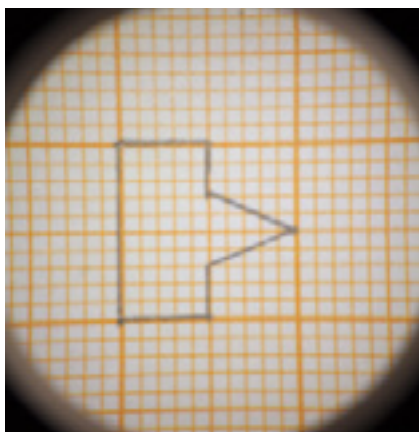
The objective of the study was to investigate whether the product had any wound healing effect. Healing of the wound can be assessed by macro photography and measuring the size of the wound area via software assisted photo analysis. Clinical photography is a key area of excellence at proderm.

ter loss (TEWL). Measuring trans-epidermal water loss using a Tewameter allows us to measure the speed of the restoration of the epidermal barrier as a secondary parameter. Other secondary parameters can include subjective efficacy assessment by participants and objective wound healing quality assessments by our trained investigators.

Suction blisters damage the skin barrier, causing an increase in transepidermal wa-



Photographic measurement and documentation of days 0,2 and 4 of wound healing progress: Current (upper row) vs Original margin (lower row).



Software assisted measurement of wound area is equivalent to traditional planimeter measurement



Study milestones



44

patients randomized



3

drop outs



-2

LPO two weeks earlier
than planned

proderm gets the job done

Our suction cup device, which provides vacuum pressure to several suction cups simultaneously, allows us to induce suction blisters on several volunteers in parallel. Social distancing during the pandemic severely limited our ability to do so since volunteers need to

sit in close proximity if the device is run at full capacity. By introducing double shifts at no extra cost for the sponsor we were able to adhere to social distancing rules and still managed to meet LPO two weeks early.

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