FIRST EVALUATION OF A CLINICAL PATHWAY USING MECHANICAL WOUND DEBRIDEMENT*, ANTIMICROBIAL HYDROBALANCE DRESSING** AND COLLAGEN DRESSING*** ON 57 PATIENTS WITH CHRONIC WOUNDS

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Introduction :

The aim of this clinical investigation was to prove the usability of a new clinical pathway using mechanical wound debridement*, an antimicrobial hydrobalance dressing** and the granulation-promoting effect of collagen*** in the daily routine.

Methods :

A multicentre (12 centers), post marketing surveillance study (PMS) was carried out to observe the clinical pathway on 57 patients with leg ulcers (n=43), diabetic foot ulcers (n=14) or pressure sores (n=2) during 8 weeks of treatment (4 visits at day 0, day 12, day 28, day 56).
After the mechanical wound debridement at day 0, wounds were treated with moisture-regulating, antimicrobial wound dressing and secondary wound dressings adapted to wound exudate until day 12. From then on until day 56, or the healing of the wound, an absorbable collagen sponge was used (Fig. 1).

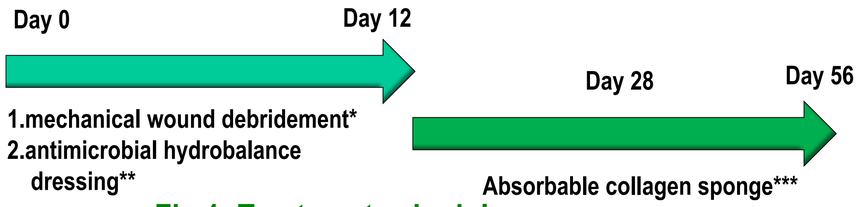


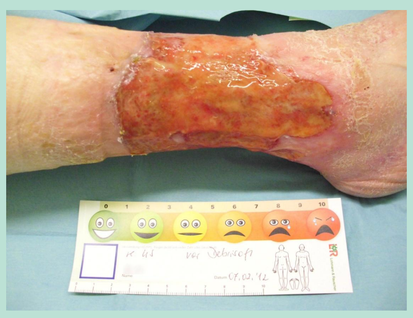
Fig 1: Treatment schedule

Results :

The application of the debridement product was rated as easy-to-use (97.4 % as “excellent” to “very good”), effective (as “excellent” to “good” by 78.9% of the users for overall performance, 74.5% for reduction of keratosis) and time efficient (87.4 % of the users needed less than 4 minutes) by the investigators. An example of the effective mechanical debridement is given in Fig 2.

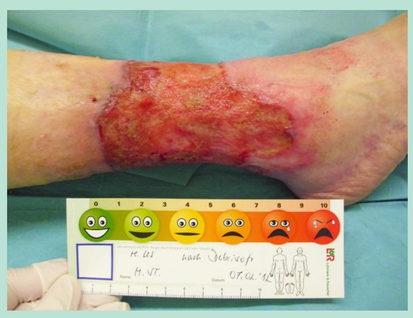
The majority of patients assessed the mechanical wound debridement as almost painless (Visual Analogue Sore [VAS] at baseline (mean) 2.14 / 2.5 during treatment and 1.75 after visit 1). After the application of the Hydrobalance product** the patients had an additional subjective reduction of pain (VAS at baseline: 2.14, after visit 1: 1.35).
The wound healing process was promoted. The wound phases shifted from 53.7/46.3 % to 25.9/74.1% (slough/necrotic to granulation/epithelization) after 8 weeks (Fig 3). No medical device related adverse event was reported by the investigators. Enclosed two case reports (Fig. 4 and 5).

Visit 1
Before debridement



Wound assessment:
- Wound bed: mucous-fibrinous coating
- Wound surrounding skin: dry and crusty debris

Visit 1
After mechanical debridement



Wound assessment:
- Wound bed: significant reduction of coating
- Wound surrounding skin: bland

Fig 2: Example of effective mechanical wound debridement

Conclusion :

The current scientific data demonstrates the usability, time efficiency and performance of this clinical pathway for diabetic foot ulcers, leg ulcers and pressure sores.

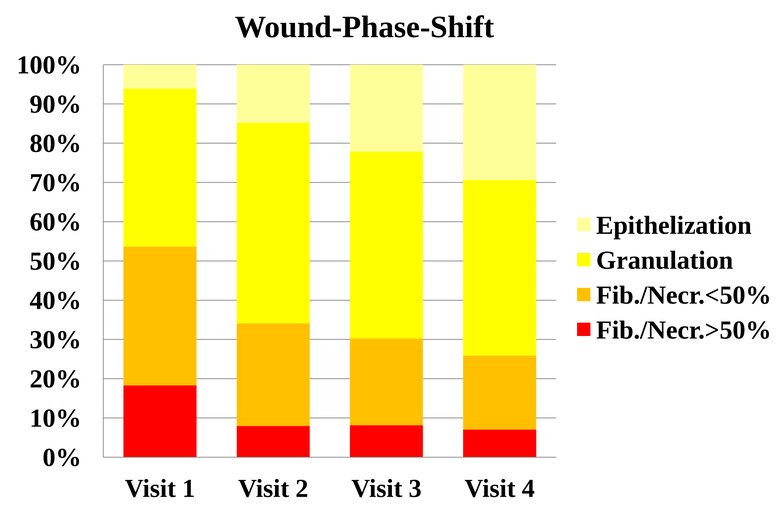
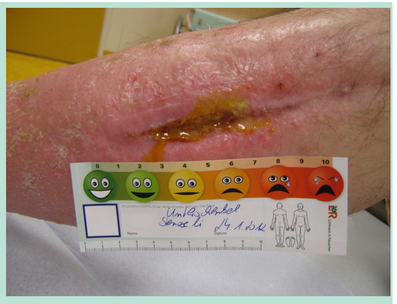


Fig 3: Wound-Phase-Shift from Visit 1 to Visit 4

Venous Leg Ulcer
- male patient
- CVI (3° acc.to Widmer)
- moderate exudation, wound size 8,4 x 1,98cm

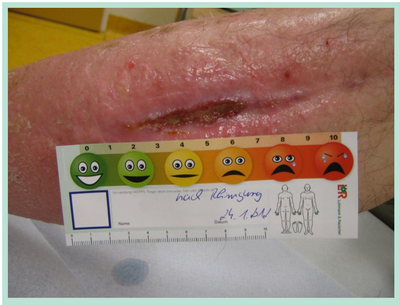
Woundhealing after Visit 4
- significant reduction of coating
- light to moderate exsudation
- reduction of wound size to about 89%

Visit 1
Before debridement



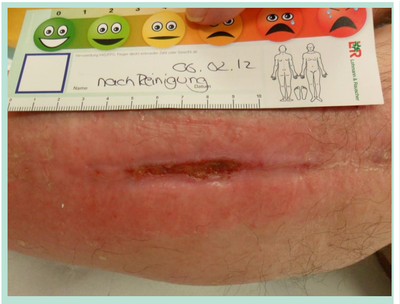
Wound assessment:
- Wound bed: slushy-fibrinous coated
- Wound edge: dry and scaly surface, redness occured

Visit 1
After mechanical debridement



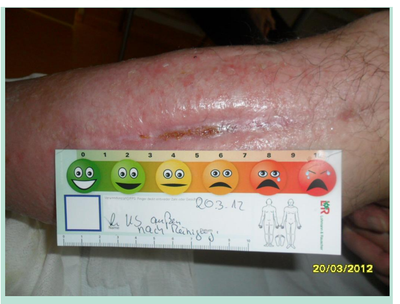
Wound assessment:
- Wound bed: clean and granulating
- Wound surrounding skin: inconspicuous

Visit 2
After mechanical debridement



Wound assessment:
- Wound bed: significant reduction of coating
- Wound surrounding skin: slighty red

Visit 4
After mechanical debridement



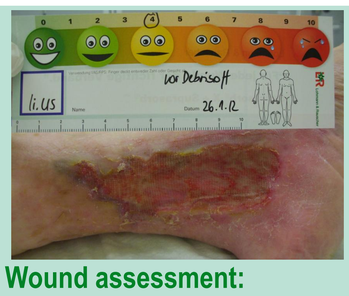
Wound assessment:
- Wound bed: slushy-fibrinous coated
- Wound edge: dry and scaly surface, redness occured

Fig 4: Case report with Venous Leg Ulcer

Venous Leg Ulcer
- male patient
- CVI (3° after Widmer)
- light to moderate exudation, wound size 9,1 x 3,1 cm

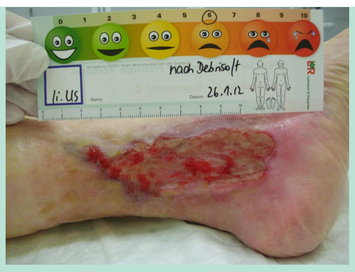
Woundhealing after Visit 4
- reduction of caoting
- light exudation
- reduction of wound size to about 81%

Visit 1
Before debridement



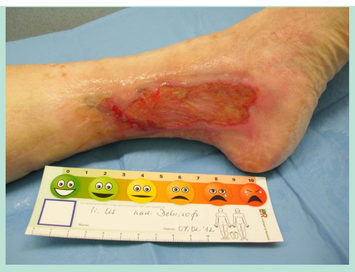
Wound assessment:
- Wound bed: dry-fibrinous coated
- Wound edge: dry and scaly surface, redness occured

Visit 1
After mechanical debridement



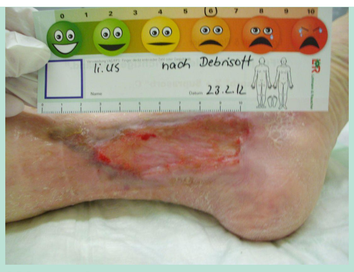
Wound assessment:
- Wound bed: significant reduction of coating
- Wound edge: redness occured

Visit 2
After mechanical debridement



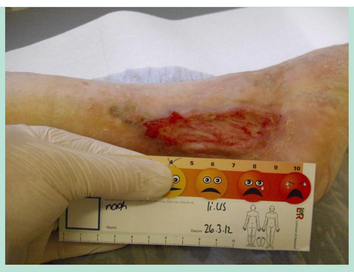
Wound assessment:
- Wound bed: significant reduction of coating
- Wound edge: inconspicuous

Visit 3
After mechanical debridement



Wound assessment:
- Wound bed: significant reduction of coating
- Wound edge: inconspicuous

Visit 4
After mechanical debridement



Wound assessment:
- Wound bed: clean, granulating
- Wound edge: inconspicuous

Fig 5: Case report with Venous Leg Ulcer

* Debrisoft; ** Suprasorb X+PHMB; *** Suprasorb C, Lohmann & Rauscher

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