

Assessment of efficacy and tolerability of a new developed hydroactive wound dressing

Stefanie de Lange¹, Michael Schmitz², Martin Abel¹

¹ Lohmann & Rauscher, Rengsdorf, Deutschland; ² MCS Medical Consulting, Oberahr, Deutschland

Aim:

The efficacy of a wound dressing including effective exudate management and pain reduction, tolerability and user/patient satisfaction are the most important factors beside the treatment of the underlying disease. Therefore a clinical study with a new developed hydroactive wound dressing* was performed to evaluate the key factors of successful wound treatment in patients with chronic wounds.

Method:

During an international, multicenter application study data have been collected regarding dressing performance (easiness of application, adaptability, shrinking, convenience, removability, improvement wound condition, protection of wound edge, skin condition and management of exudate) and rating of pain (NRS=numeric rating scale 0-10). Conclusion and general notes took place after the last visit

Results:

64 patients (4 patients with respectively 2 wounds) with 68 wounds and different aetiologies (burns=2, lower leg ulcer=38, diabetic foot syndrome=5, pressure ulcer=4, donor sites=8, other=8) have been included into the statistical evaluation (male=28, female=36).



Mean age is 69,9 years, 77,4 % wounds are superficial and 22,6% deep at the first visit. The wounds exist in median since 6,1 months (0,5 – 31 months). 92,5 % are placed on foot/leg/hip, 1,5% on back trunk/ fundament/ os sacrum, 3% on arm/elbow/ shoulder, 3% on front of trunk. Infection was assessed in 17,9 % (n=12). Pain level was stated from the patients with 3,37 (VAS).

Dressing performance (understandability instruction of use, easiness of application, shrinkage of dressing, removability [non adherence, in one piece], improvement of wound, wound edge, skin condition, management of exudate, uncomplicated use, reduction of maceration, would you use it again) was assessed in median with 1,51 (1=excellent, 2=very good).

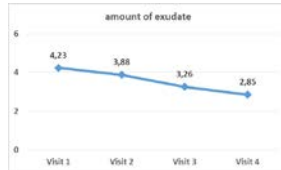
Regarding patient convenience (softness, non-adherence, removability in one piece), the hydroactive dressing was assessed in median with a quality of 1,74. Improvement of wound condition was confirmed in 95,2 % of all cases.



Opposite the first visit infection was assessed in 2 cases at visit 4. All other cases have been declared as not infected (p=0,010).

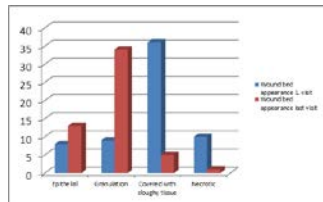


Amount of exudate was assessed as 4,26 (0 = no, 10 = highest exudate level) in the beginning. However, wounds of all exudation grades (low, moderate, severe) had been treated successfully with the hydroactive dressing. During treatment the exudation grade remained nearly unchanged for low exuding wounds and a decrease could be observed for moderate and severe exuding wounds. On a 10-point-scale (0 = no exudate, 10 = highest amount of exudate), exudation was scored with 4,23 (visit 1), 3,88 (visit 2), 3,26 (visit 3) and 2,85 (visit 4).



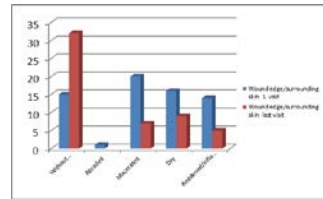
Wound bed appearance has been scored at the first visit as epithelial in 8 cases, as granulating in 9 cases, as covered with sloughy tissue in 36 cases and as necrotic in 10 cases.

At the last visit, wound bed appearance was scored as epithelial in 13 cases, as granulating in 34 cases, as covered with sloughy tissue in 5 cases and as necrotic in 1 case.



Wound edge/surrounding skin has been assessed at the first visit as without abnormality (n=15), abraded (n=1), macerated (n=20), dry (n=16) and reddened/inflamed (n=14).

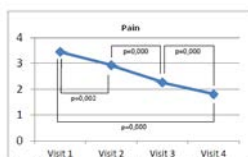
At the last visit, wound edge/surrounding skin has been assessed as without abnormality (n=32), abraded (n=0), macerated (n=7), dry (n=9) and reddened/inflamed (n=5).



Vertical fluid absorption



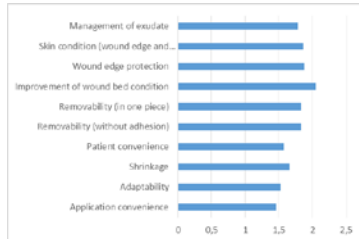
Significant pain reduction was demonstrated (3,37 [VAS] at visit 1, 1,80 at visit 4, p=0,000).



Secondary dressings**:



All study parameters under examination (efficiency, user satisfaction, patient satisfaction and tolerability and safety) fulfilled the requirements given in the study protocol. All parameters which could be answered with a verbal ranking of excellent (=1) up to insufficient (=6) have been evaluated with a median verbal rating of "very good" (=2).



Pain decreased significant from visit 1 up to visit 4 (p=0,000), wound bed condition increased from visit 1 up to visit 4 (visit 1 median 2,83 = covered with sloughy tissue, visit 4 median 1,89 = granulating).

Additional questions showed a high user satisfaction. All additional questions have been answered in median with yes (Dressing stayed in situ?: Application uncomplicated in most condition?: Wound edge protected and risk of maceration reduced?: Does Liquacel offer an effective exudate management?: Did the wound condition improve?: Would you use Liquacel again?). Sole exception presents the question "Number of dressing changes reduced". This was answered with a median of 1,64 (=no).

Conclusion:

Efficacy of Suprasorb® Liquacel is confirmed by clinical effectiveness as well as by results of patient convenience. The results and the wide range of indications offer a noticeable facilitation in daily routine. Pain reduction and high patient convenience leads to better quality of life and treatment satisfaction of the patient.