

Clinical performance of a hydrogel dressing in the management of chronic wounds – a prospective application study in 81 patients

SUMMARY

In a prospective, multicentre, ambulant application study, 81 patients (average age 67 years) were treated with the Hydrosorb comfort hydrogel dressing. The majority of the patients had chronic wounds, which were one year old on average. At the beginning and end of the study, the physicians evaluated the condition of the wounds and the pain experienced by the patients. They were treated with Hydrogel comfort for an average of twelve days and the dressing was changed every 4 days. The wound status improved markedly in the course of the study. The proportion of the wound surface that was covered with slough fell from 62.7% to 23.1%. At the same time, the area covered by granulation and epithelial tissue increased by 11.9 and 15.1 percentage points, respectively. The wound area decreased from 4.7 x 2.9 cm at the start to 3.7 x 2.3 cm. Other parameters that improved with the Hydrosorb treatment were the degree of exudation and the condition of the perilesional skin. The patients also reported markedly less pain. Whereas 29.6% of the patients reported no pain at the beginning of the study, this proportion increased to 56.3% at the final assessment. As the treating physicians emphasised, the documentation sheet provided with Hydrosorb comfort proved to be helpful in monitoring and documenting the course of wound healing.

Conclusion: chronic wounds can be treated effectively with Hydrosorb comfort. The hydrogel dressing promotes the wound healing process, reduces wound pain and thus improves the patients' quality of life.

Introduction

When the skin is injured, the body initiates a cascade of processes that eventually lead to a re-epithelialisation of the wound area and re-establishment of the skin's barrier function (1). If the precisely coordinated interplay of inflammatory cytokines, mitogenic growth factors, extracellular components and enzymes such as proteases is disturbed, stagnation of the repair process can occur. The result is a chronic wound. The most chronic wounds such as leg ulcers, pressure ulcers and diabetic foot ulcers have an underlying systemic disease process, which persistently interferes with biochemical and physiological processes in the wound area. As a result, the healing process ceases in the inflammatory phase and becomes deadlocked (2).

Chronic wounds are of various origins and have different aetiologies. Vascular causes such as venous insufficiency, arterial occlusive disease, diabetic angiopathy and neuropathy - sometimes in combination – are the most common systemic disorders. At the local level, infections, and the presence of a foreign body in the wound can delay wound healing. In addition, prevailing systemic diseases include malnutrition, malignant cachexia, autoimmune diseases and systemic co-medication (3).

Taking a systematic and disease-specific diagnosis of these local and systemic factors is a prerequisite for successful wound treatment (4). Because of the complex pathophysiology of a chronic wound, therapy should not be directed only toward isolated local factors. Rather, a more holistic approach to treatment should be taken. The basis of every therapy is causal treatment or amelioration of the underlying disease, for instance,

treatment of venous hypertension in chronic venous insufficiency. Furthermore, only when deficits of the macro- and microcirculation in the wound area are eliminated and blood, oxygen, and nutrient supply are optimally corrected, can a wound dressing successfully support the healing process of an ulcer (5).

Several parameters of the wound state influence the choice of the appropriate wound dressing. Important parameters include size and location of the wound, the degree of exudation, presence of slough, necrosis, and possible signs of infection as well as the healing phase of a wound at any given time. No single wound dressing can deal with all of these different parameters. Therefore, a number of different hydroactive wound dressings are available to the wound care professionals, most specifically tailored to ensure a physiologically moist wound milieu, which promotes the repair process. During the treatment, the condition of the ulcer should be inspected regularly and the local and systemic treatment should be adjusted if any changes are diagnosed (6).

Hydrogel dressings are indicated for chronic wounds which exhibit only slight exudation. Because of the high water content of up to 90% of these dressings, they are able to keep granulation tissue and fresh epithelial tissue moist and protect them from external mechanical stress and provide a barrier to secondary infection from the environment (7).

The present application study investigated the clinical efficacy and tolerability of the Hydrosorb comfort hydrogel dressing on wound healing in patients who suffered mainly from chronic ulcers that were difficult to address therapeutically.

Table 1 Patient characteristics (n =81)

Women	42 (51.9%)
Men	39 (48.1%)
Age	66.8 years (±15.1 years; median 68.4 years; range 31.2 to 97.7 years)
Age of wound	365 days

Hydrosorb comfort is a transparent hydrogel dressing made of absorbent polyurethane polymers containing about 60% water. When applied to the wound, Hydrosorb supplies the tissue with moisture. At the same time, the hydrogel absorbs excess wound exudate and locks it into the gel structure. This ensures moisture balance in the wound and promotes the production of epithelial and granulation tissue.



Because of the high proportion of water, Hydrosorb comfort is also indicated when dry slough or necrosis has to be separated from the base of the wound. The Hydrosorb comfort employed in the study is surrounded by a hypoallergenic adhesive film. The transparency of the hydrogel enables the condition of the wound to be inspected at any time. The user can also document changes in the wound size during treatment with a foil. After the wound dressing has been placed on the wound, the wound size can be traced on the film using a pen and the film is then removed and stored in the patient file. After several dressing changes, the treating doctor can track the course of healing by comparing the respective wound sizes.

Material and methods

Outpatients with chronic or acute wounds of different aetiologies in 15 German medical centres (eight surgeons, four general physicians, one internal medicine office and two teaching hospitals) were eligible to participate in the prospective, multicentre application study. The requirement for including the patients in the study was that treatment with the hydrogel dressing was clinically indicated. One wound per patient was treated in the study. No patients were excluded, in line with chronic wounds encountered mostly in daily practice. The attending physicians were free to treat any patient with chronic wounds, irrespective of age, sex or comorbidities or the origin of the wound. Each patient was treated individually in the study according to their medical history and diagnosis. Overall, three dressing changes were documented. At the initial examination, the investigators recorded the patients' age, sex, general health state and comorbidities, age and size of the wounds as well as previous local and systemic treatments

and co-medications using a standardised questionnaire. At the beginning and end of the study, the investigators evaluated the condition of the wound by recording the proportion of slough, granulation and epithelial tissue, the extent of exudate, the condition of the perilesional skin and patient-reported pain. At the final examination, the wound care professionals assessed the clinical efficacy, tolerability, and the handling of Hydrosorb comfort. The patients were also asked about their experiences with the hydrogel treatment.

Results

The investigators documented the course of treatment of 81 patients. 39 patients (48.1%) were male and 42 (51.9%) were female (table 1). The average age was 66.8 years (±15.1 years, range 31.2 to 97.7 years). The general health was assessed as very good in 16 patients (20%) and age-appropriate in 45 patients (55%). 20 patients (25%) had a reduced physical state due to comorbidities. According to the attending physicians'

Table 2 Aetiology of the wounds (n= 81)

Cause	proportion in %
Venous leg ulcer	19.8
Arterial leg ulcer	7.4
Mixed leg ulcer	12.3
Decubitus ulcer	9.9
Diabetic pressure ulcer	9.9
Diabetic gangrene	7.4
Acute traumatic wound	7.4
Burn	8.6
Other	17.3

Wound condition

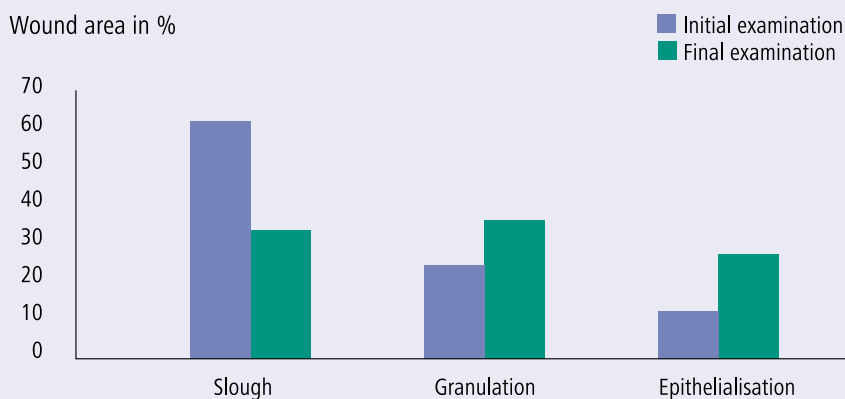


Fig. 1 Condition of the wound before and after treatment with Hydrosorb comfort (n = 81)

description, 44 of the patients (54%) were included in the study because previous treatment of the wound had failed to achieve improvement. For 30 (37%) the treatment with the hydrogel dressing was the first treatment of the wound. 6 patients (7.4%) were treated with the hydrogel because the phase of wound healing had changed. 8 of the 81 patients withdrew from the study prematurely, two of them at the first dressing change and 6 further patients at the second dressing change. The reasons were maceration, in particular, and other adverse reactions in the region of the wound margins.

Aetiology of the wounds

The wound care professionals treated wounds with Hydrosorb that had arisen mainly because of vascular diseases (table 2). Venous and arterial ulcers were the most common wound types with 40%. The patients had suffered from their ulcers for an average of 365 days (range 0 days to 20 years, median 92 days).

Previously used local wound dressings

Topical wound care consisted of foam dressings, silver-containing wound dressings, wound dressings with antiseptic and antibiotic agents, ointment dressings and hydrocolloids, sometimes in combination, were most commonly applied in 46 patients prior to inclusion in the study.

Co-medication and therapy

At the start of the study, 35 patients (43%) were on systemic medication. The patients were taking anticoagulants, antibiotics, oral antidiabetic regimens, steroids and analgesics in particular. In 8 patients (9.9%), the treating physicians combined the hydrogel dressing with another wound dressing: 3 patients had an amorphous hydrogel, 2 patients an alginate dressing and 3 patients had a wound dressing containing silver applied to their wounds. To treat the chronic venous insufficiency, compression therapy was prescribed for 24 patients. In 22 patients, measures to relieve the pressure on the wound were employed and in a further 16 patients the doctors documented accompanying measures such as wound debridement or elevation of the treated limb.

Wound outcomes

The patients were treated with the hydrogel dressing for an average of 12.1 days and dressings were changed every 4 days. In the course of the study with the hydrogel the proportion of the wound area covered with

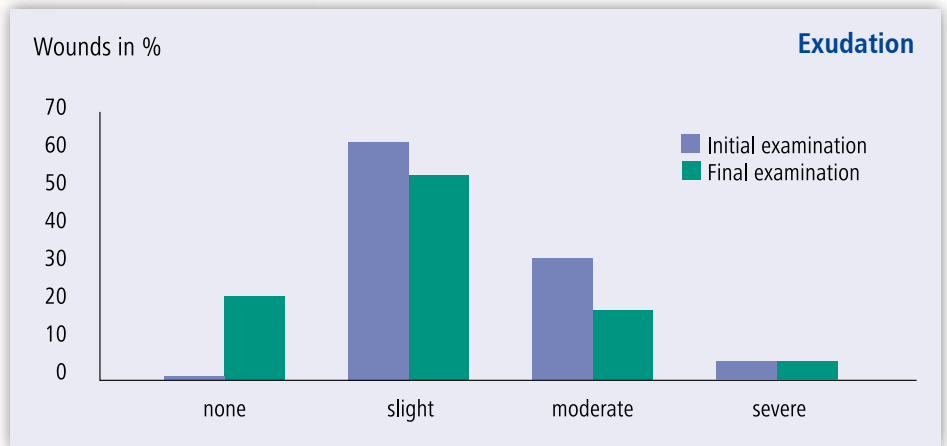


Fig. 2 Change in the degree of exudation in the course of the study (n = 81)

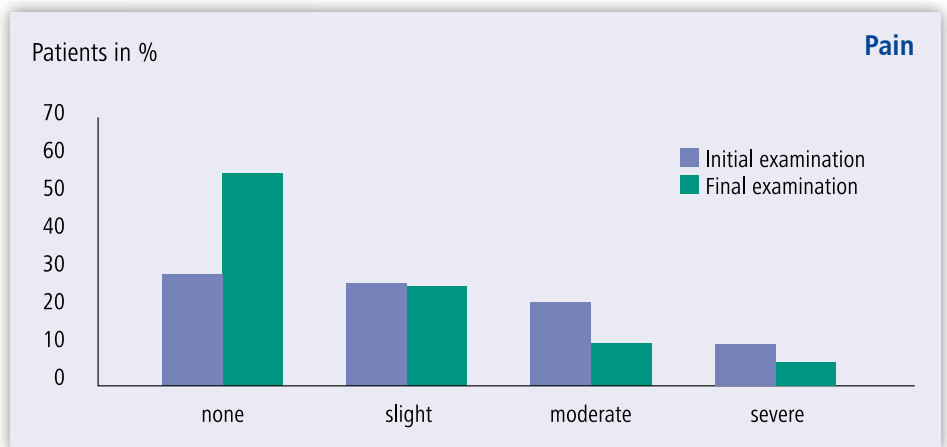


Fig. 3 Change in pain felt by the patients in the course of the study (n = 81)

slough fell from 62.6 to 23.1%. At the same time, the area covered with granulation and epithelial tissue markedly increased (fig. 1). The wound size (length x width) fell from 4.7x 2.9 cm to 3.7 x 2.3 cm. Five wounds were completely re-epithelialised at the end of the study.

Apart from the condition of the wound, the degree of exudation also improved (fig. 2).

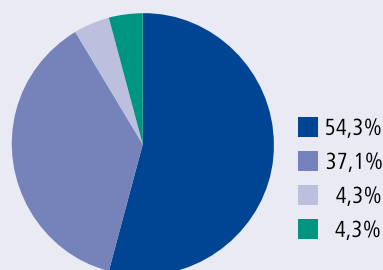
The proportion of patients whose wounds were not exuding increased from 0% at baseline evaluation to 22%. At the same time, the proportion of moderately and heavily exuding wounds fell by more than half from 47% to 23%. Fewer pathological symptoms were also diagnosed in the perilesional skin (table 3).

Table 3 Condition of the perilesional skin before and after treatment with hydrogel dressing (multiple nominations possible)

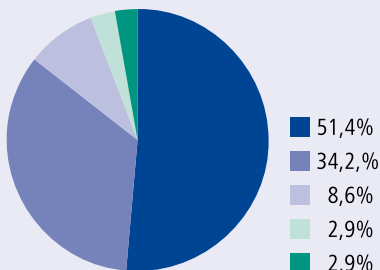
Diagnosis	Initial examination	Final Examination
No pathological findings	33	47
Signs of inflammation	46	23
Erythema	16	8
Hyperthermia	11	3
Oedema	10	8
Infection	9	4
Perilesional maceration	20	18
Maceration	8	5
Eczema	1	6
Hyperkeratosis	10	7
Blisters	1	0
Other	2	8

Assessment of Hydrosorb comfort treatment by the patients

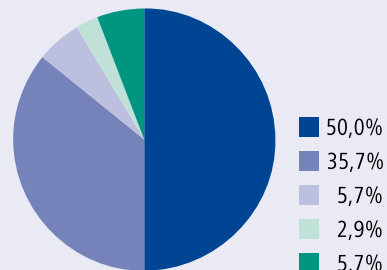
Tolerability



Comfort during wear



Overall impression



■ very good ■ good ■ satisfactory ■ adequate ■ poor

Fig. 4 Assessment of the wound treatment by the patients (n = 70)

Patient-reported pain

The number of patients reporting wound pain decreased markedly in the course of the three dressing changes. Whereas 29.6% of the patients reported no pain at the start, this proportion rose steadily to 56.3% at the final evaluation (fig. 3). The number of patients with severe pain was almost halved from 11.1% to 6.3%.

Dressing performance ratings by physicians and patients

The investigators assessed the hydrating characteristics, the ease of removal and the good contact with the base of the wound as very good or good in over 90% of the treatments (table 4). Good or very good skin tolerability was recorded in over 90% of the treated patients. The physicians had a good or very good overall impression of the treatment with the hydrogel in 83% of the treatment.

In the opinion of the treating physicians, the condition of the wounds had improved or markedly improved in over 85% of the patients. The condition did not change in 8.6% of the patients and it worsened in 6.1%. 70 of the 81 patients assessed the tolerability and wearing comfort of the hydrogel (fig. 4). The overall impression was graded as very good or good by over 85% and as satisfactory by 5.7%.

Documentation aid to assess the course of healing

The investigators used the Hydrosorb comfort documentation aid at each dressing change in 15 patients (18.5%). The documentation aid was used partially in a further 40 treatments (49.4%). In every third wound treatment (32.1%), the aid was not used as other documentation methods were preferred. If the documentation aid was used, its use was described in 54 of the 55 cases as very

easy or easy and in one case as satisfactory. In 43 cases, the doctors assessed the documentation aid as helpful or very helpful in assisting wound documentation.

Discussion

The prospective and multicentre application study showed that the hydrogel dressing promotes production of granulation and epithelisation. Because this was a small nonrandomised and non-comparative clinical observational trial, it can only give some first information about the clinical performance and tolerance of the treatment with the hydrogel dressing. It is not a proof of efficacy, but provides a real-world outcome evaluation of the wound care provided by medical and nursing staff, in an unselected panel of patients, mostly reflecting non-healing, intractable wounds encountered in daily practice. During the local treatment with the hydrogel, the proportion of the wound area

Table 4 Assessment of Hydrosorb comfort treatment by the physicians (results in %)

	very good	good	satisfactory	adequate	poor	not assessable
Contact with the wound base	43.2	49.4	4.9	1.2	1.2	0.0
Adjustment to the body modellability	45.7	49.4	13.6	2.5	1.2	0.0
Exudate management	28.4	54.3	9.9	1.2	4.9	2.5
Hydrating characteristics	54.3	40.7	1.2	2.5	0.0	1.2
Skin tolerability	60.5	30.9	1.2	0.0	6.2	1.2
Separation of necrosis	29.6	23.5	1.2	0.0	1.2	44.4
Adhesion	46.9	32.1	12.3	1.2	6.2	1.2
Removability	64.2	32.1	2.5	0.0	1.2	1.2
Overall impression	46.5	37.0	6.2	3.7	6.2	0.0

covered with granulation tissue increased from 25% to 37% and the proportion covered with epithelial tissue from 12% to 28%. These results are consistent with other studies in which the local treatment with hydrogel dressings promotes the healing process of chronic wounds (8, 9).

Chronic wounds cause pain in many patients, which can interfere with quality of life (10,11). To relieve wound pain, the choice of a suitable hydroactive wound dressing is of crucial importance (12). Hydrogel dressings hydrate and cool the wound and therefore have an analgesic effect. This was shown by numerous studies in which burn wounds, venous ulcers and dermabrasions were treated with hydrogels (13). As they can also be removed without traumatising the wound bed, the cell vitality of the newly formed granulation and epithelial tissue remains intact (14). The pain-reducing effects were also observed in the patients who were treated with Hydrosorb comfort in the current study. The number of pain-free patients without pain increased from 30% to over 56% while at the same time the proportion with severe pain decreased from 11% to 6%. The attending physicians confirmed that the hydrogel dressing can be removed from the wound without difficulty when the dressing is changed. They assessed the removability as very good or good in over 96% of the treatments.

Another advantage of hydroactive compared to traditional wound dressings is their cost-effectiveness in the treatment of chronic ulcers. Hydroactive wound dressings can be left on the wound longer compared to traditional dressings and therefore have to be changed less frequently. In the present application study, the wound care professionals changed the hydrogel dressing every 4 days on average. Since the hydroactive dressing also provides a physiologically moist milieu, the wounds heal faster, which again shortens the treatment time. This also improves the quality of life of the patients, who are often troubled by their chronic wound for months or even years. If the total treatment costs are compared (material for dressings and other aids, frequency of dressing changes, staff costs etc.), hydroactive wound dressings are more cost-effective than, for instance, gauze dressings (15).

In the treatment of chronic ulcers with hydrogel dressings, maceration in the wound area can occur because of the constant

water release especially in the case of more exudative wounds. The ability to absorb excessive exudate is much lower compared with other hydroactive dressings such as hydrocolloids or foams (7). According to the investigators, this was also the main reason for discontinuation of the treatment with the hydrogel dressing. To avoid maceration, it is therefore important to inspect the wound and also the perilesional skin regularly in order to identify pathological changes promptly and adjust the local wound treatment accordingly (16, 17). Adequate care of the wound margins must also be ensured. Especially in elderly patients, the skin around the ulcer is very fragile and susceptible to maceration, oedema and erythema (18). Closure of the defect is possible only when the perilesional skin is also intact as the proliferation and migration of cells from which the epithelial and granulation tissue is produced are initiated by the skin surrounding the wound (19). Skin protection creams have been proven as effective skincare measures (20). Nevertheless, hydrogel dressings have clear advantages when little wound exudate is produced and the dressing change intervals become longer. Here their transparency allows wound bed inspection without the necessity to remove the dressing. This unique property avoids traumatic dressing changes and adds cost benefits.

Conclusion

The non-randomised, non-comparative trial in an unselected panel of 81 patients, who are characteristic for internist and general medical practices and outpatient clinics, suggests that chronic wounds, especially those of venous origin, can be treated effectively with Hydrosorb comfort. By providing a moist wound environment, the hydrogel dressing promotes the healing process, reduces wound pain and thus improves the patients' quality of life.

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