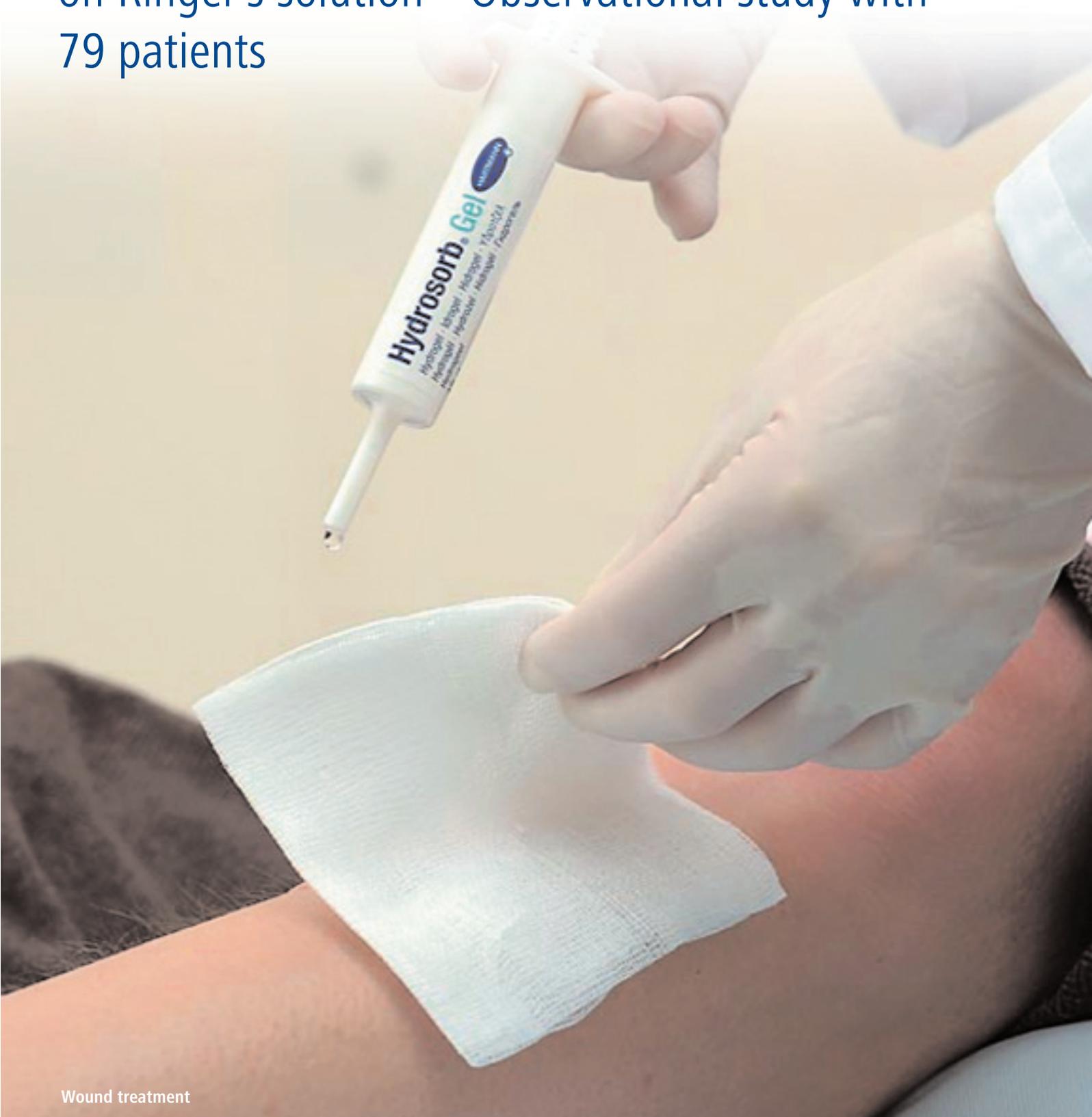




Hydrosorb Gel

Efficacy and tolerability of an amorphous gel based on Ringer's solution – Observational study with 79 patients



Summary

The enhancement of wound healing, the tolerability and the pain-reducing properties of the new amorphous Hydrosorb Gel were investigated in an observational study. A total of 79 patients with chronic (mostly venous) ulcers or non-chronic (mostly traumatic) wounds were treated for an average period of 10 days. The wounds had persisted for 2 months on average at the start of treatment. An improvement in wound status was observed in the course of treatment: coatings were reduced and injuries to wound margins receded. At the same time, there was increased formation of granulation and epithelisation tissue. Increasingly fewer patients complained of wound pain. Overall, wound therapists and patients were very satisfied with treatment with Hydrosorb Gel. For clearly over 80% of the wounds, physicians and nursing staff evaluated the overall impression as well as the handling and the various product properties as "good" or "very good". This favourable assessment was, to a substantial extent, due to the product's particular moisture delivery, tolerability to the skin and handling. Patient acceptance of treatment with Hydrosorb Gel was also very high. More than 90% of the patients said their overall impression of the product was "good" or "very good". The excellent tolerability of the gel had a significant role in this assessment.

The objective of wound treatment is to support or restore physiological wound healing by eliminating disturbing elements (1). A basic requirement for adequate wound healing is therefore wound cleansing by debridement and removal of material contaminated with bacteria such as necroses and coatings.

In the early phases of wound healing, wound cleansing is an autolytic process achieved by the effects of enzymes released by neutrophils migrating into the wound area where they carry on endogenous debridement (2). Necrotic tissues and eschar are liquefied and detached from healthy tissue (3). Although this cleansing process occurs naturally in acute wounds, it can be supported by a suitable local wound treatment, thus speeding the healing process (4). When produced in excess, fibrin, fibrinogen and other macromolecules may, especially in chronic wounds, bind the growth factors and signal molecules needed for the wound healing process, making them unavailable for wound healing (4). The healing process comes to a halt and cannot move on to the actual repair phase.

Wound treatment with hydrogels is suitable for breaking down non-vital tissue and detaching it atraumatically from healthy tissue. As a result of their high moisture content, hydrogels can rehydrate coated wounds with light exudation, thus initiating the healing process (5). Laboratory investigations already show that the amorphous Hydrosorb Gel is set apart from competitor products by its particular ability to deliver moisture to the wound (figure 1). The gel also contains Ringer's solution to maintain a physiological environment,

thus supporting the formation of granulation tissue. The study presented below looked at how Hydrosorb Gel meets the exigencies of clinical practice.

Materials and methods

The enhancement of wound healing, the tolerability and the pain-reducing properties of Hydrosorb Gel were investigated in a multi-centre study involving 79 patients with wounds of various geneses. 22 physicians and nursing staff documented the course of study for an average period of 10 days. This duration was equivalent to three dressing changes, with the last dressing change occurring at the final examination. At the inclusion examination data concerning age, sex, general condition, age of wound and additional therapeutic measures were collected. The success of wound treatment with Hydrosorb Gel was evaluated on wound status development. Also documented were wound site abnormalities and the development of pain.

Upon completion of treatment with Hydrosorb Gel, the treating persons evaluated various product properties and also indicated to what extent the product met their expectations. Patients were asked to rate satisfaction with the product, tolerability and wearing comfort during treatment with Hydrosorb Gel.

Results

The average age of the 44 female and 35 male patients was 68 years. The general condition of the patients was evaluated by the treating persons as "very good" in 13% of the cases. The condition was rated as "appropriate for the age" in 48% of the cases, and as "re-

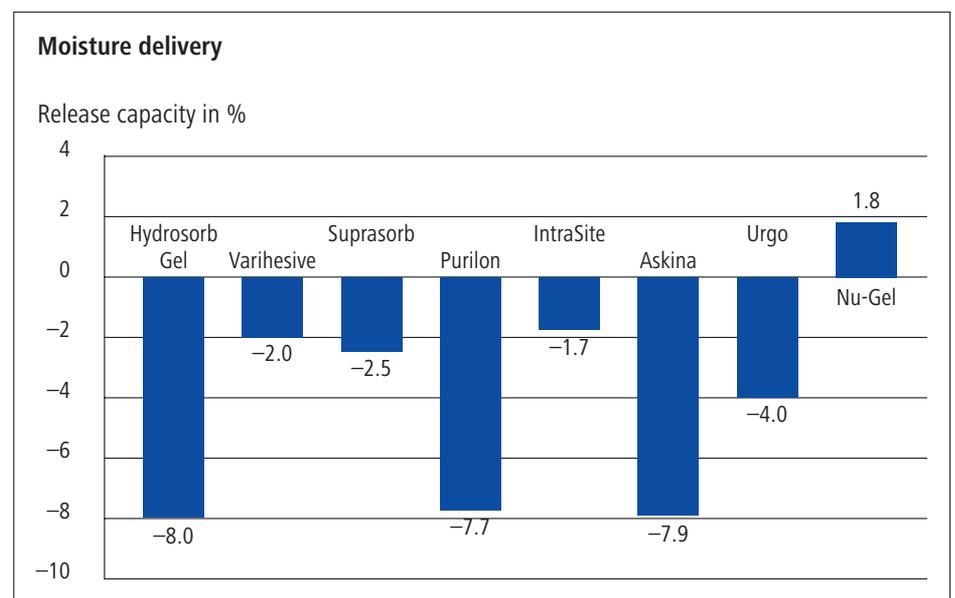


Figure 1: Compared with other products, the moisture delivery of Hydrosorb Gel is particularly high.

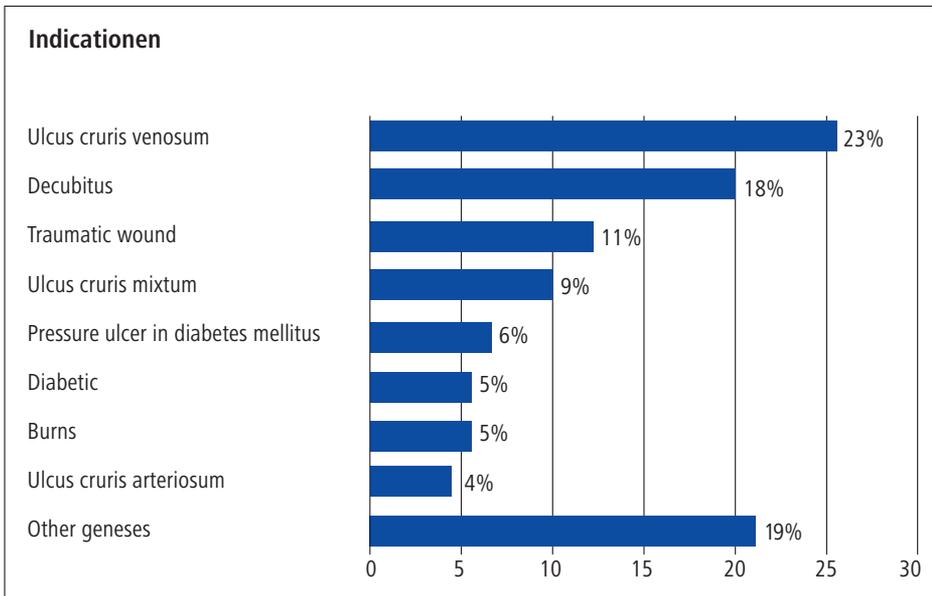


Figure 2: Aetiology of treated wounds.

duced" in 39% of the cases. 64% of the patients had a chronic wound. 35% of these patients (altogether 23%) had a venous leg ulcer (Ulcus cruris venosum) (figure 2).

The other chronic wounds were classified in 18% as decubitus, in 9% as arterial-venous leg ulcers (Ulcus cruris mixtum), in 6% as pressure ulcers in diabetes mellitus and in 5% as diabetic foot. The non-chronic wounds (36%) were classified in 11% as traumatic wounds and in 5% as burns. The patients had had their wounds for an average of 2 months.

27 patients (34%) received compression treatment for causal therapy of their chronic, predominantly venous wounds. In 28 patients (35%) measures were taken to relieve pressure. Most patients (78%) had Hydrosorb Gel

combined with secondary dressings, mainly foam or gauze dressings, in the course of treatment.

Most wounds showed light to moderate exudation

In 85% of the patients, wounds showed light to moderate exudation at the start of treatment, and some wounds were covered with coatings.

Effective wound cleansing promoted wound healing

The moisturizing properties of Hydrosorb Gel were reflected in the product's cleansing effect. The moisture, stored as Ringer's solution in the gel, broke down coatings. The germ-laden material was absorbed by the gel and thus removed from the wound. Whilst 16% of

the wound area was necrotic on average at the start of the study, this percentage decreased to 8% by the final examination (figure 3). The average proportion of fibrin coatings in the wounds was almost halved in the course of treatment, decreasing from 40% to 21%. The removal of coatings impeding the healing process also encouraged fibroblast and endothelial cell migration and proliferation, and defect filling with healthy tissue. The average proportion of granulation tissue in the wound area was 35% at the start of treatment, compared with 49% at the final examination. The adequately prepared wound base also facilitated epithelial cell migration, resulting in a more than twofold increase in mean epithelial area from 9% at the start of the study to 21% at the final examination.

Wound site protection through balanced moisture delivery

A healthy wound site is an essential prerequisite for the formation of granulation and epithelial tissue. Hydrosorb Gel absorbed the wound fluid of these wounds, typically showing light to moderate exudation, thus protecting tissues from irritation and substantially improving the wound site. Whilst only one in three wound sites was unremarkable and almost one in four wound margins showed evidence of maceration at the start of the study (table 1), more than half of the wounds were found to have developed an unremarkable wound margin and as few as 9% of wound sites still showed evidence of maceration at the final examination.

Table 1: Wound site abnormalities decreased substantially.

Irritations	Start	End
None	27	41
Oedema	20	13
Overheating	18	6
Maceration	17	7
Erythema	16	11
Eczema	8	2
Hyperkeratosis	7	4
Infection	5	2
Blisters	2	0
Others	9	4

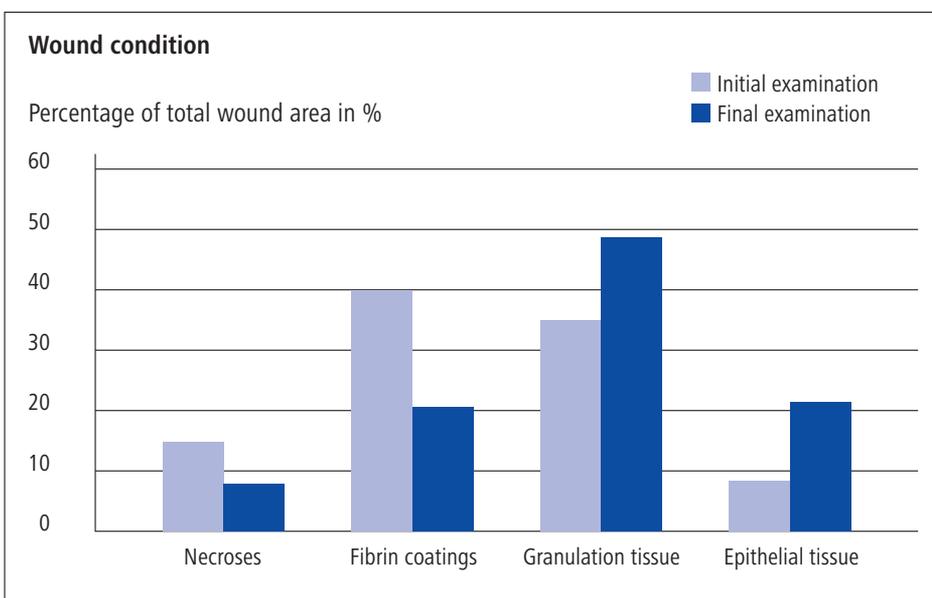


Figure 3: Coatings were reduced, and the formation of healthy tissue promoted.

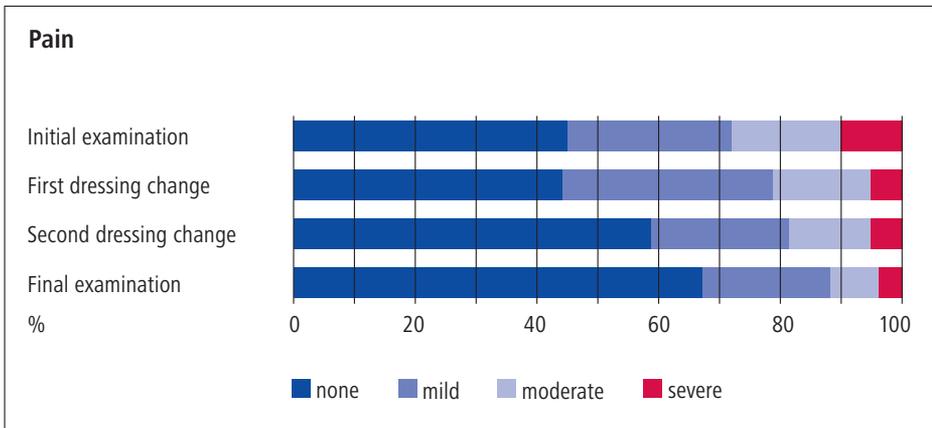


Figure 4: Increasingly fewer patients complained of wound pain.

Fewer patients complained of wound pain

Significant improvements in wound status and wound site conditions reduced the incidence of wound pain in the course of treatment. Whereas at the start of the treatment 28% of patients had been affected by mild or severe pain, this was reduced during the course of treatment and still true in just 11% of cases (figure 4). At the same time, the proportion of patients with no pain during the course of treatment rose from 44% to nearly 65%.

The gel's cooling effect and the atraumatic removability of gel residues from the wound had significant roles in pain reduction, especially during dressing changes. The treating physician and nursing staff found that Hydrosorb Gel was easy or very easy to remove from the wound in 63% and 35% of cases, respectively. None of the respondents evaluated removability as difficult. In most cases the gel could be removed by rinsing with saline solution and/or dabbing with a sterile swab.

Favourable evaluation by physicians and nursing staff

Treating persons using Hydrosorb Gel confirmed that the product promoted wound healing. Respondents said the condition of wounds treated with Hydrosorb Gel improved significantly during the course of treatment. Wound status was evaluated improved or substantially improved at the final examination in 49% and 36% of cases, respectively. In one patient the wound situation had clearly deteriorated after the first dressing change, and treatment had to be stopped early. This wound showed increasing exudation during the course of treatment so that the wound margins developed worsening maceration under these conditions.

Hydrosorb Gel users were highly appreciative especially of the product's properties and handling characteristics (figure 5).

97% of respondents evaluated gel handling and applicability as "good" or "very good". The long syringe tip enables safe application

even in deeper wounds. The syringe also facilitates one-handed application until completely empty and accurate dosing. The consistency of the gel is another feature that adds to the product's ease of handling. The gel is firm enough to prevent it from running off, and liquid enough to conform optimally to the wound base. In 94% of the cases the viscosity of the gel was evaluated as "good" or "very good". None of the users rated the gel "too fluid" or "too firm". The moisturizing properties of Hydrosorb Gel were evaluated during the course of treatment as "good" or "very good". Due to the high moisture content, necrotic tissue was rehydrated and easy to detach.

The detachability of non-vital tissue was rated "good" or "very good" for 88% of wounds covered with necrotic tissue. Given the superior product properties of Hydrosorb Gel, 94% of users said that their overall impression of the product was "good" or "very good". In fact, respondents found that the product fulfilled or exceeded their expectations in 61% and 21% of cases, respectively. For as few as 3% and 1% of treated wounds, user expectations were "not really fulfilled" or "not fulfilled".

More than 90% of patients evaluated tolerability as "good" or "very good"

Patient satisfaction with treatment with Hydrosorb Gel was also very high (figure 6). Almost half of the patients found that the product was "very good" on wearing comfort and tolerability. 44% or 45% respectively, evaluated Hydrosorb Gel on these features as "good".

The ease of gel removability during dressing changes reduced the occurrence of pain, thus improving tolerability. In addition, the pleasantly smooth surface, the high moisture content and the padding effect of the gel made for high wearing comfort. A total of 94% of the patients said that their impression of the product was "good" or "very good".

Discussion

This prospective multi-centre study showed that treatment with Hydrosorb Gel supports the wound healing processes in the cleansing and repair phases. The geneses of the wounds included in the study were variable, reflecting the spectrum of wounds treated in physicians' practices and outpatient departments. Mostly, the wounds were chronic and partially covered with necrotic tissue and fibrin coatings, and characterised by light to moderate exudation.

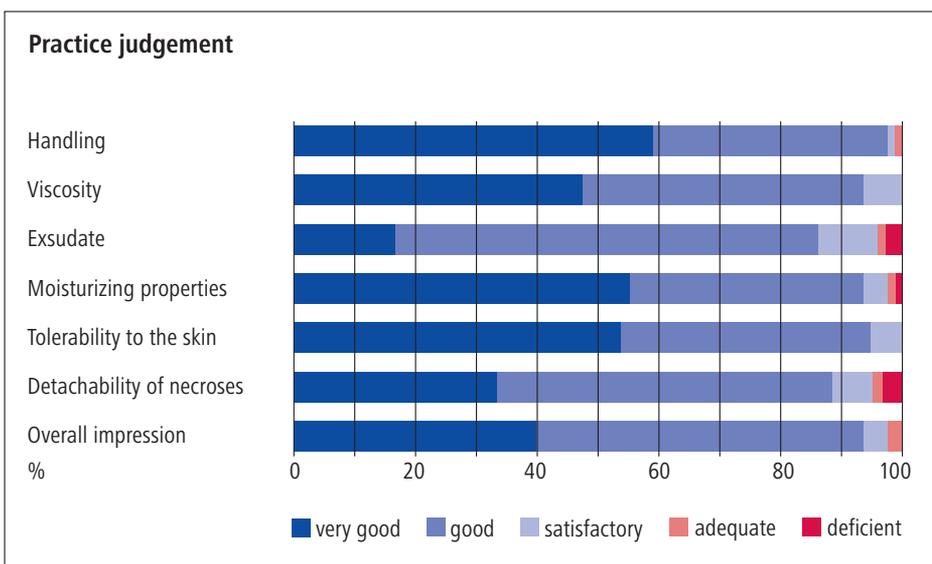


Figure 5: The properties of Hydrosorb Gel were evaluated as „good“ or „very good“ in more than 80% of cases.

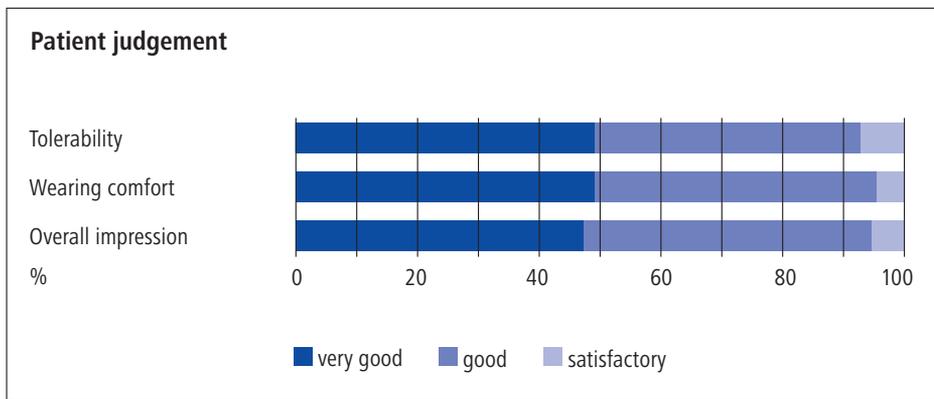


Figure 6: More than 90% of the patients evaluated the product as “good” or “very good” on wearing comfort and tolerability

Non-vital tissue is a focus for infection, prolongs the inflammatory reaction, mechanically blocks contraction of wound margins, and impedes re-epithelisation. The removal of dead tissue is therefore an essential step for successful wound treatment (4). Hydrosorb Gel supported autolytic wound debridement by reducing necrotic coatings from 16% to 8% and fibrin coatings from 40% to 21%. These results confirm the findings of an earlier study showing that supporting autolytic cleansing with a suitable hydroactive dressing can effectively remove coatings from wounds and thus promote healing. The result achieved with autolytic debridement was at least equivalent to that obtained with enzymatic wound cleansing (6). As well as facilitating wound cleansing, Hydrosorb Gel supported the progression of wound regeneration. The area covered with granulation tissue increased from 35% to 49%, and at the same time the epithelised area increased from 9% to 21%.

Having had adverse experiences in the past, affected patients tend to associate pain with most steps involved in local wound treatment such as wound cleansing and dressing change (7). Fear of pain is a frequent motive for patients not to return to their physician for a dressing change, thus delaying or even worsening wound healing. The ease of gel residue removability from the wound during dressing changes and the pleasant material features of Hydrosorb Gel resulted in overall good tolerability and high acceptance by patients. The percentage of patients who were free of pain increased from 44% to 65% by the final examination.

Skin irritations of the wound margins and wound site, such as macerations, are complications that may occur during wound treatment with amorphous hydrogels (8). This is caused by excess aqueous wound exudate

coming into contact with the surrounding skin for a prolonged period of time, thus causing damage. As a result, the defect fails to close because new growth of vessels and cell migration from the damaged neighbouring tissues are not possible. The absorption capacity of Hydrosorb Gel was sufficient for absorbing the wound fluid of wounds showing light to moderate exudation so that the wound sites improved overall, and macerations decreased from 21% to 9% during the course of treatment. Treatment had to be stopped only in a single case because that wound showed increased exudation and wound margin maceration during treatment with Hydrosorb Gel. The wound situation had changed during the course of treatment, making it necessary to switch to a more absorbent wound dressing.

Conclusions

The moisturizing properties of Hydrosorb Gel are suitable to support autolytic wound debridement by liquefying and detaching eschar and coatings. Thanks to the moist wound environment, wound regeneration is promoted so that Hydrosorb Gel can be used across wound healing phases including the cleansing as well as granulation and epithelisation phases. The ease of gel removal from the wound enables atraumatic dressing changes, impacting favourably on tolerability.

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