The results of a non-interventional trial involving the application of Hydrocoll® to chronic wounds

Summary

The new Hydrocoll hydrocolloid dressing was tested in a non-interventional trial involving 1245 patients with mainly chronic ulcers. In the course of three applications, a significant increase in wound granulation and epithelialisation revealed that Hydrocoll has a supportive influence on wound healing. In 85% of cases, the application of Hydrocoll resulted in an impressive reduction in the layers of crust that form over the wound. For a third of the patients, the exudate changed from one that contains some pus to one that is predominantly purely serous.

In the opinion of the doctors, achievement of the treatment objective was "good" or "very good" in at least 81.7% of cases.

This was also the case in patients for whom previous treatment methods had been unsuccessful (613 patients). Among the patients included in the trial, there was evidence of various factors that have been shown to delay wound healing: a high average age, a poor general state of health (415 patients) and relevant concomitant medication (898 patients).

More than 90% of the doctors regarded their expectations of the treatment as having been met or surpassed. The majority said that the dressing was easy to apply and remove. Adhesion and comfort were also deemed to be very good or good in most cases.

The expectations of most of the patients (90.6%) with regard to the treatment were either met or surpassed.

The moist environment accelerates wound healing

For about 40 years, scientific studies have shown that open skin wounds heal more quickly and qualitatively better in a moist environment than a dry one. Modern hydrocolloid dressings create the ideal conditions for moist wound treatment. The entire wound healing process, from the exudative phase through the granulation phase to the epithelialisation phase, is supported and encouraged under occlusive conditions.

Surplus wound exudate is absorbed by the inner layer of the dressing as are dead material, bacteria and toxic substances. This moist wound environment preserves the activity of neutrophilic granulocytes against microorganisms. As a result of high carbon dioxide pressure, blood vessels develop quickly and granulation tissue forms. Unlike dry wound treatment, scabs do not form and so wound healing is not restricted to the lower layers.

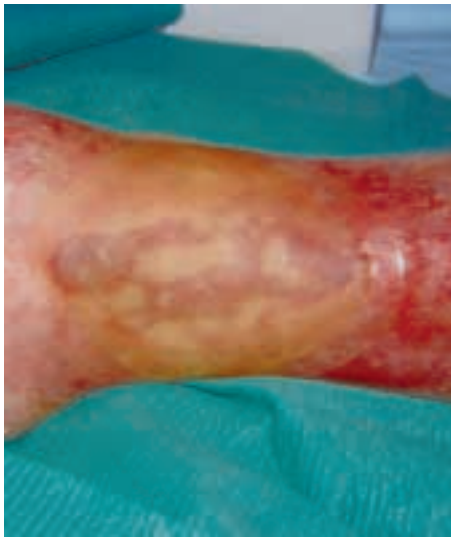
Epithelial cells divide more quickly, migrate more easily and grow over the surface of the wound causing the wound to heal more quickly.

Hydrocolloids – modern wound healing in a moist environment and easy to use

The inner layer of a hydrocolloid dressing is composed of a self-adhesive elastomer with embedded hydrocolloid particles. These particles absorb wound secretion, turning into a gel-like mass in the process. This layer of gel prevents the dressing from sticking to the wound and protects the newly formed tissue. The top layer is a semi-permeable polyurethane film, which prevents water and bacteria from penetrating the dressing.

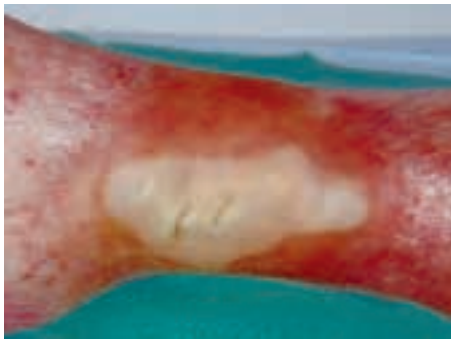
Patients are very happy to wear hydrocolloid dressings because they can be worn in the bath and shower and therefore they are able to maintain their usual standards of personal hygiene. Even if they have been worn for a long time, hydrocolloid dressings can be removed without any problems or skin irritation.

If the surface of the wound is not infected, hydrocolloid dressings can be used successfully during all phases of wound healing. Areas of indication for this dressing include various acute and chronic wounds. In particular, wounds that produce small to medium amounts of exudate are ideally suited to the application of hydrocolloid dressings. The absorption capacity of the dressing means that sloughy wounds can also be cleaned effectively.



Features of the new Hydrocoll hydrocolloid dressing

The new Hydrocoll can absorb fluid from the wound even more quickly and thoroughly thanks to an improvement in the structure of the inner layer. It effectively prevents wound exudate from leaking and therefore a premature dressing change. It is even easier to use because it is more flexible and extremely adherent yet very kind to the skin. The condition of the wound can be assessed as soon as the dressing has been removed as most wounds contain virtually no gel residue. Time-consuming wound irrigation is not necessary.



Task/contents

In order to test the features of the new Hydrocoll hydrocolloid dressing from HARTMANN, 1245 patients with acute and chronic wounds were treated within the frame-work of a non-interventional trial.

At the beginning of the trial and in the course of four visits, i.e. three dressing changes, the doctor providing treatment examined the wound in order to monitor its condition and the healing process. The condition of the wound surface, the quantity and composition of the exudate and the condition of the edges of the wound were recorded in a structured questionnaire. As the patient progressed, crusts, granulation and epithelialisation were also assessed.

Finally, the doctors assessed the product features of Hydrocoll with regard to absorbency, skin tolerability and ease of use, among other things. They also stated whether their expectations of the product had been met.

The patients also assessed how successful treatment had been from their point of view. In addition, they were asked about the tolerability, comfort and effectiveness of the treatment.

Patient profile

A total of 1245 patients were included in the trial. The patients that took part in this non-interventional trial were mainly patients with chronic wounds (442 patients) and patients for whom previous treatment methods had been unsuccessful (613 patients). 804 of the patients were female and 436 of the patients were male.

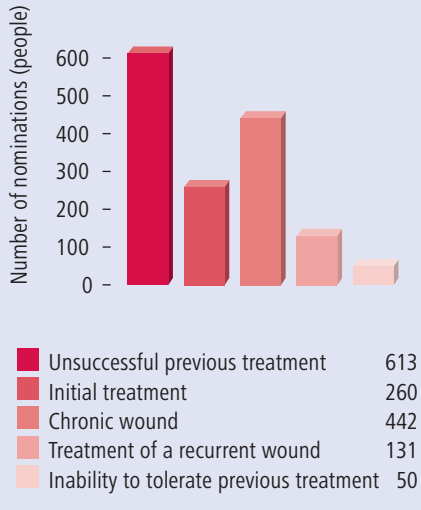
The average age of the women treated was 72.2 and the average age of the men treated was 65.7 (there was no information available about the age of 5 of the patients). The majority of the patients were in a good general state of health or an appropriate general state of health for their age. A third of the patients were in poor health. Old age and poor health are important factors for decelerated wound healing.

Diagnoses

66% of the patients treated were suffering from a leg ulcer (of these, 50% had a venous leg ulcer, 13% had a mixed aetiology leg ulcer and 3% had an arterial leg ulcer). 12% were suffering from a pressure ulcer, 8% from acute traumatic wounds and 10% from a pressure sore in diabetes mellitus or diabetic gangrene. 3% of the patients had burns. A smaller percentage were treated for tumours and radiation damage.

Reasons for treatment

613 patients were treated because previous treatment methods had been unsuccessful and another 442 had chronic wounds. For 260 patients, this was the first time that their wound had received treatment and 131 patients were treated for the recurrence of a wound. 50 patients were treated because they had been unable to tolerate previous treatments (participants were able to give more than one reason for the treatment with Hydrocoll). In 39% of cases, chronic wounds were given as the reason for treatment with Hydrocoll.



Concomitant measures

Analgesics (545 patients), anticoagulants (133), systemic corticoids (33), immunosuppressives (9) and non-steroidal antiinflammatory drugs (178) were taken as concomitant medication before the trial commenced.

709 patients received concomitant compression therapy. The majority of these used compression bandages (488) although a smaller number were given compression stockings (183). 10 patients received both forms of treatment.

Results

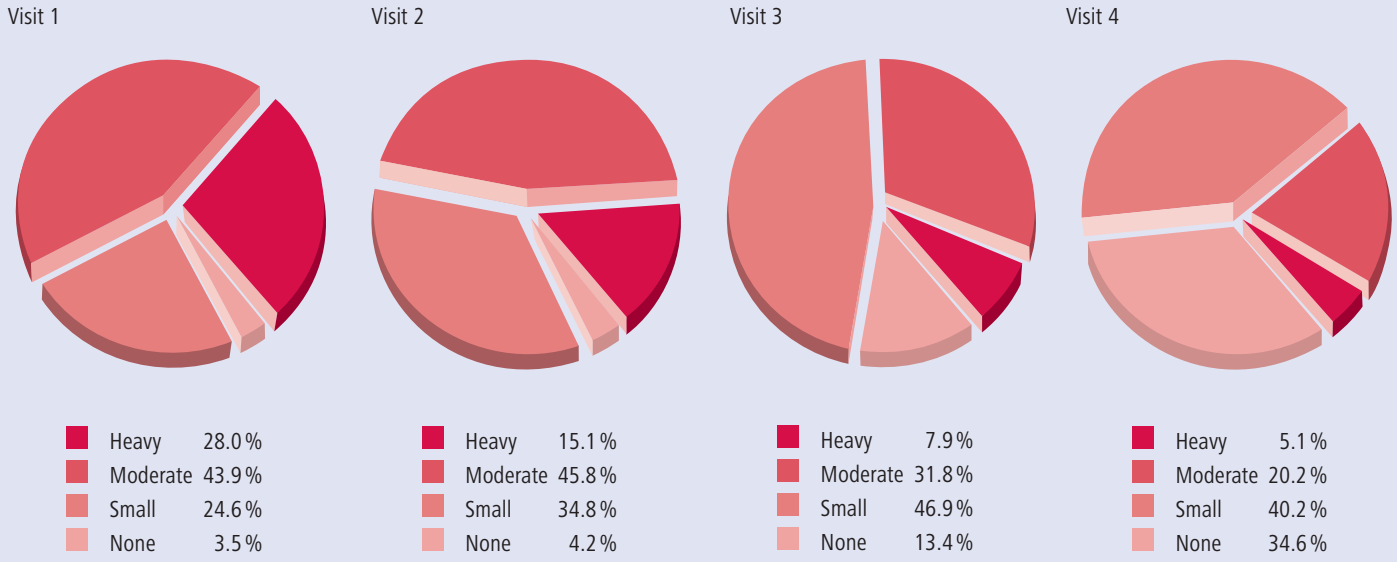
Quantity of exudate

When treatment of the wounds with Hydrocoll commenced, most of the wounds were producing moderate (43.9%) or large (28.0%) quantities of exudate. Small quantities of exudate (24.6%) and no exudate (3.5%) were less common.

In contrast, a significant decrease in the quantity of exudate was recorded in the course of the visits. At visit 4, after 3 dressing changes, the wounds of only 5.1% of the patients were still producing large quantities of exudate and those of 20.2% of the patients were producing moderate quantities. In contrast, those of 74.8% of the patients were producing either no (34.6%) or small quantities (40.2%) of exudate.

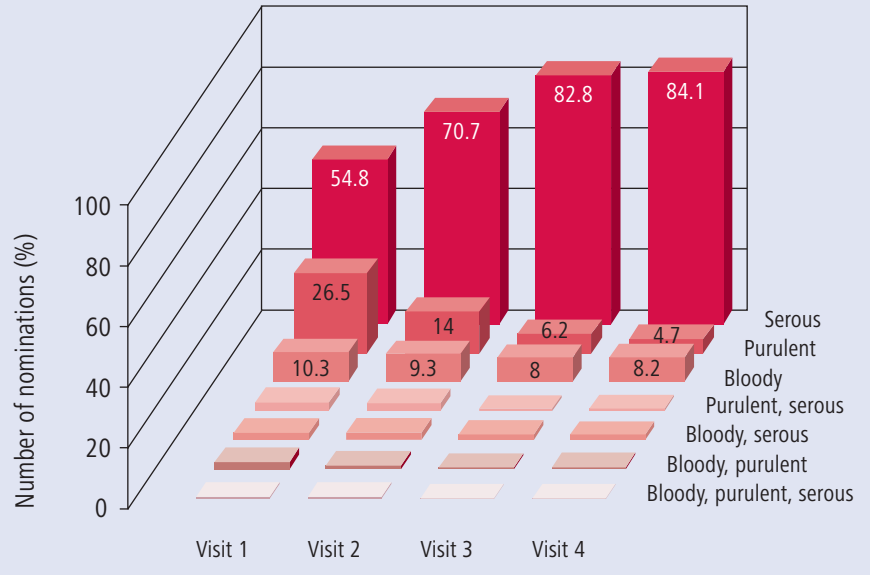
The drop in the quantity of exudate suggests on the one hand that Hydrocoll is very absorbent. On the other hand, it also shows that the wound healing process, which passes from the exudative phase into subsequent phases, is being supported.

Changes in the exudate quantity



Composition of the exudate
At the beginning of the trial, the exudate was described as serous in 54.8% of the wounds. Of the remaining 45.2%, some were purulent or bloody in parts (8.4%) and some contained only pus (26.5%) or only blood (10.3%). After Hydrocoll had been applied three times, the appearance of the exudate became purely serous (84.1%). The purulent (4.7%), bloody (8.2%) and mixed forms (3%) decreased very significantly during treatment with Hydrocoll.

Changes in exudate composition



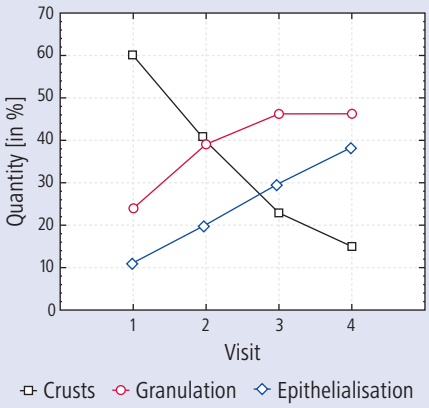
At the start of the trial, exudate that contained pus was observed in almost one in three of the wounds treated (32.2%). The marked decrease to 5.7% following three Hydrocoll applications suggests that in the majority of cases (84.1%), Hydrocoll effectively absorbed dead material, bacteria and pus and that the wound was stimulated to clean itself until purely serous exudate formed. The moist wound environment supports immunocompetent cell activity in the defence against microorganisms.

Wound healing progress
The progress of the wound healing process throughout treatment with Hydrocoll was significantly positive. While 60.4% of all wound surfaces had a crust at the start of treatment, only 15.1% of them had a crust after the Hydrocoll treatment had been completed. Treatment with Hydrocoll led to a very significant reduction in wound crusts. As a result, granulation tissue, which had only been present in 24% of the wounds at the start of treatment, was observed in at least 46.2% of the wounds at the 4th visit.

Composition of the exudate
At the beginning of the trial, the exudate was described as serous in 54.8% of the wounds. Of the remaining 45.2%, some were purulent or bloody in parts (8.4%) and some contained only pus (26.5%) or only blood (10.3%). After Hydrocoll had been applied three times, the appearance of the exudate became purely serous (84.1%). The purulent (4.7%), bloody (8.2%) and mixed forms (3%) decreased very significantly during treatment with Hydrocoll.

At the start of the trial, exudate that contained pus was observed in almost one in three

Wound healing progress



decrease to 5.7% following three Hydrocoll applications suggests that in the majority of cases (84.1%), Hydrocoll effectively absorbed dead material, bacteria and pus and that the wound was stimulated to clean itself until purely serous exudate formed. The moist wound environment supports immunocompetent cell activity in the defence against microorganisms.

Wound healing progress
The progress of the wound healing process throughout treatment with Hydrocoll was significantly positive. While 60.4% of all wound surfaces had a crust at the start of treatment, only 15.1% of them had a crust after the Hydrocoll treatment had been completed. Treatment with Hydrocoll led to a

Assessment of product-specific features by the doctor
The doctors providing the treatment assessed the features of Hydrocoll by awarding them one of the following grades: very good, good, satisfactory, adequate or unsatisfactory. Hydrocoll's ability to absorb wound secretion was deemed to be very good in 49.1% of cases and good in 43.5% of cases. It was reported to be satisfactory in 5.8% of cases and adequate or unsatisfactory in 0.9% and 0.7% of cases respectively.

Conformability was reported to be very good in 46.8% of cases and good in 46.6% of cases. It was judged to be satisfactory in 6.3% of cases and adequate or unsatisfactory in only 0.2% and 0.1% of cases respectively.

Adhesion was judged to be very good in more than half of the patients (53.3%) and good for 38% of them. It was satisfactory in 7.5% of cases and adequate or unsatisfactory in 0.9% and 0.3% of cases respectively. Skin tolerability was also judged to be very good or good in 91.6% of cases and satisfactory in 6.4% of cases. It was adequate or unsatisfactory in 1.2% and 0.7% of cases respectively.

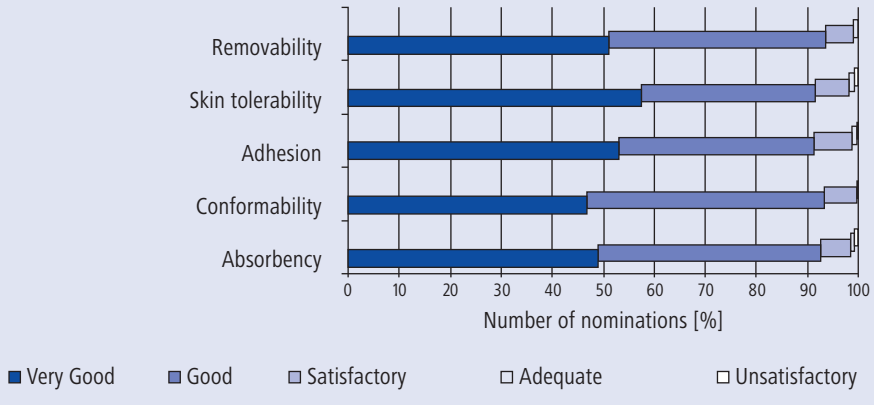
In terms of how easy it was to remove, the doctors rated Hydrocoll very good or good in 93.8% of all cases, satisfactory in 5.6% of cases and adequate in 0.9% of cases. It was not regarded as unsatisfactory for any of the patients.

All of the product features assessed were judged to be very good or good in over 90% of cases. They were judged to be unsatisfactory in less than 1% of cases.

Assessment of treatment by the doctor
The doctors providing the Hydrocoll treatment reported that their overall impression of it was very good or good in 89.9% of all cases, satisfactory in 6.9% of cases, adequate in 1.8% of cases and unsatisfactory in 1.4% of cases. In terms of how easy it was to use, the material was judged to be very good or good in 96.3% of all cases, satisfactory in 3.2% of cases, adequate in 0.3% of cases and unsatisfactory in only 2 cases (0.2%). The tolerability of Hydrocoll was also judged to be good or very good in 93.9% of cases. Achievement of the treatment objective was judged to be very good or good in 81.7% of all cases, i.e. for more than 4 out of 5 patients. It was rated satisfactory in 11.5% of cases, adequate in 3.0% of cases and unsatisfactory in 3.9% of cases.

The doctors' expectations of the treatment were met or surpassed in 93.8% of cases and not really or not met in 6.2% of cases. More than 90% of the doctors judged the ease with which the material was used and the tolerability of treatment with Hydrocoll to be very good or good.

Product-specific assessments



Whilst 50 patients were included in the trial because they had not tolerated previous treatments, the tolerability of Hydrocoll was only regarded as unsatisfactory for 16 patients. The remainder tolerated the treatment and it was deemed very good or good for the vast majority of them.

Almost half of the patients (613) used Hydrocoll because previous treatment methods had been unsuccessful. Another 442 had chronic wounds and 131 patients were treated due to the recurrence of a wound when using other treatment methods. The fact that the treatment objective was achieved using Hydrocoll for 81.7% of these wounds, which had often shown long periods of resistance to other previous treatments, is even more remarkable if you assume that the average age of the patients included in the trial was high. Old age is an important factor for delayed wound healing as is a poor general state of health, which was evident in at least a third of the patients. In addition, a high number of the patients included in the non-interventional trial received concomitant medication in the form of drugs that can also delay wound healing, e.g. analgesics, anti-coagulants, systemic corticoids, immunosuppressives and non-steroidal anti-inflammatory drugs. These drugs were prescribed 898 times in total.

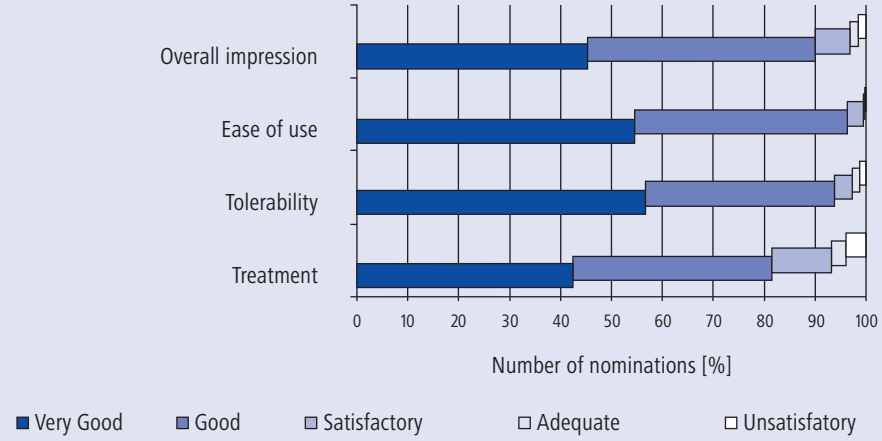
Assessment of treatment by the patient

More than 90% of the patients found the tolerability of Hydrocoll to be very good or good. For 5.2% it was satisfactory and for 1.8% it was adequate. 1.9% (23 patients) found the tolerability unsatisfactory. Hydrocoll also achieved excellent results with regard to comfort: 90.5% rated it very good or good, 8.1% rated it satisfactory and 1.0% rated it adequate. Only 0.5% (6 patients) reported that they found Hydrocoll unsatisfactory.

From the patients' point of view, achievement of the treatment objective was very good or good in 78% of all cases, satisfactory in 13.9% of cases and adequate in 3.4% of cases. 4.6% of the patients reported an unsatisfactory level of success. 86.2% of the patients said that their overall impression of Hydrocoll was very good or good. It was satisfactory for 8.9% and adequate for 3.3%. 1.6% of the patients formed an unsatisfactory overall impression. The expectations of most of the patients (90.6%) with regard to the treatment were either met or surpassed. Only 9.4% reported that their expectations had not really or not been met.

The vast majority of the patients judged the tolerability and comfort of Hydrocoll to be very good or good and the overall impression of more than 4 out of 5 patients was very good or good. Achievement of the treatment objective was only deemed unsatisfactory by 4.6%. In view of the fact that the majority of patients had chronic wounds and were included because previous treatment had been unsuccessful, this is certainly a remarkable assessment.

Product-specific assessments



Conclusion

This non-interventional trial provides impressive evidence of the effectiveness of Hydrocoll in the treatment of chronic and acute wounds. The application of Hydrocoll supports wound healing during all of its phases.
Even wounds of long duration like those of the majority of the patients in this trial showed progress toward healing. Hydrocoll was well accepted by the patients on account of its excellent adhesion and very good patient comfort. The fact that it is easy to apply and remove makes the work of doctors and nursing staff easier. Good absorption of wound exudate prevents premature dressing changes, which saves money and increases compliance.

DE – PAUL HARTMANN AG
89522 Heidenheim

AU – PAUL HARTMANN Pty. Ltd.
Waterloo, NSW 2017

EG – PAUL HARTMANN Egypt S.A.E.
Giza, 12515

HK – PAUL HARTMANN Asia-Pacific Ltd.
Hong Kong

SG – PAUL HARTMANN Pte Ltd.
Singapore 609 143

UK – PAUL HARTMANN Ltd.
Lancs/Heywood OL10 2TT

US – HARTMANN-CONCO, Inc.
Rock Hill, SC 29730

Please visit our website at www.hartmann.info.

SD VA/E (1203) 087 458/0