Treatment of chronic wounds:
Clinical trial confirms the efficacy and tolerance of the foam dressing PermaFoam®

Summary

The enhancement of wound healing and the tolerance of the hydroactive foam dressing PermaFoam were investigated in an observational study in 841 patients. Over 80% of the patients were suffering from chronic, poorly healing wounds, such as, venous leg ulcers (Ulcera cruris venosa), decubital ulcers or diabetic ulcers, which they had had for an average of 1.5 years. Approximately two-thirds of the patients received compression treatment at the same time as the PermaFoam treatment, and over 80% were taking medication.

Use of the foam dressing markedly improved the wound-healing tendency. Coatings and exudation reduced and the wounds formed granulation and epithelial tissue. During treatment, the patients experienced much less wound pain, and the wounds decreased in size by more than one-third. The enhancement of wound healing was also observed in venous leg ulcer (Ulcus cruris venosum) patients receiving concomitant compression treatment. The good clinical efficacy is reflected in the judgement of the physicians and patients alike. Between 80% and 90% of the physicians rated the efficacy and tolerance as well as the ease of handling of the wound dressing as very good or good. Over 90% of the patients rated tolerance and wearing comfort as very good and good.

The medical management of patients with chronic wounds, besides involving causal treatment of the underlying condition, also consists of the stage-adapted use of modern, hydroactive wound dressings. The wound-healing stage (cleansing stage, granulation and epithelisation stage), the extent of necrosis, coating and exudation as well as possible infections all have to be considered when selecting a suitable wound dressing. The foam dressing PermaFoam is indicated for moderately to severely exuding wounds in the exudative or proliferative healing stage. Particularly in cases of chronic problematic wounds, such as leg ulcers (Ulcera cruris) of various geneses, decubitus and up to 2a degree burns, it guarantees a physiological wound milieu and encourages wound healing.

While the treatment of problematic wounds with PermaFoam has proven its value in practice, until now there has been no clinical trial that has scientifically studied the efficacy of outpatient treatment. This omission has now been rectified with the foregoing observational study.

Over 800 patients were treated with PermaFoam

306 registered physicians with their own practices (mainly dermatologists and general practitioners) took part in the observational study, treating a total of 841 patients with PermaFoam using a standardised questionnaire, the following information was collected at the start of the investigation and over the course of three appointments (three dressing changes): age, sex, general condition, type of wound, prior treatment, concomitant medication, as well as how long the patient had had the wound. Furthermore, the wound-healing course was rated on a 5-point scale using various wound parameters (coatings, granulation, epithelisation, exudation and wound pain). The physicians also assessed the wound site at the initial and final examinations.

After the end of the trial, the physicians rated the efficacy and product properties of the foam dressing. In addition, they had to estimate the extent to which their expectations of wound treatment with PermaFoam had been met. The patients were also asked about the tolerance and wearing comfort of the foam dressing after the end of the treatment.

One in two patients had a venous leg ulcer (Ulcus cruris venosum)

The majority of the patients were women (64%), with a mean age of 73 years. The men participating in the trial were on average much younger, at 66 years of age. The mean age of the patients as a whole was 70 years. Only 12% of patients were in a very good general condition in the judgement of the treating physicians, who rated the general condition as consistent with age in most cases (60%).

„The wound size reduced by more than one-third."

More than one in four patients (28%) were in a debilitated general condition. Of the 841 patients treated during the observational study, almost half had a venous leg ulcer (Ulcus cruris venosum) (48%). The other wounds were classified in 13% as arterial-venous leg ulcers (Ulcus cruris mixtum), in 11% as decubital ulcers, in 10% as diabetic ulcers, in 4% as burns, in 4% as ulcers of arterial origin and in 11% wounds of various geneses, including traumatic or postoperative wounds (Fig. 1). Overall, more than 80% of patients had a chronic wound (Ulcera cruris (leg ulcers), diabetic ulcers or decubital ulcers).

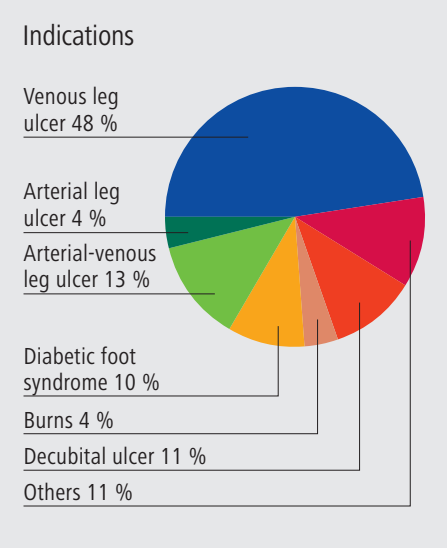

Fig. 1 Indications: More than 80% of patients had a chronic wound.

The patients had had their wounds for an average of 1.5 years before enrolment in the trial, with 75% of wounds being one year old or less. Prior treatments included hydroactive (hydrocolloid, alginate and so on) and conventional wound dressings (dressings and gauzes) as well as ointments. A total of 134 different products had been used.

Measures used concomitantly with PermaFoam treatment

Two-thirds of the patients received compression treatment at the same time as the PermaFoam treatment. In 30% of cases, PermaFoam with an adhesive edge was used, in 70% of cases, the product without adhesive edge was used. 39% of patients were taking analgesics, 19% of the patients were taking antibiotics, 12% were taking non-steroidal anti-inflammatory drugs and 10% of patients were taking anticoagulants.

Summarising the analysis of patient characteristics, the majority of patients exhibited several risk factors capable of interfering with the wound-healing process. Besides increased age and a debilitated general condition, the use of medication can also have an adverse effect on wound healing.

Less coatings and exudation, more granulation and epithelisation

In the case of most of the wounds treated in the trial, the transition from the inflammatory to the proliferative wound-healing stage had been impaired. At the start of the trial, hardly any of the wounds had formed epithelial tissue, and in only a few were the physicians able to observe florid granulation tissue. However, treatment with PermaFoam brought about a lasting improvement in the wound-healing tendency. The coatings and exudation in the wounds decreased markedly over the course of the three appointments. Once the foam dressing had conditioned the wound base, granulation tissue and subsequently epithelial tissue were able to form in most wounds.

The results in detail

Whereas at the start of the observational study more than one in three wounds were heavily or completely coated, this was true in only 3% of wounds at the end. At the same time, the proportion of wound surfaces with no or only a mild coating rose from 31% to 88% after three dressing changes (Fig. 2). Similarly, wound exudation decreased. More than one in two wounds were severely or most severely exuding at the start of the trial, compared with only 8% at the end.

As PermaFoam absorbed the excessive wound exudate, stored it, and effectively cleansed the wound, thus creating the foundations for the transition from the inflammatory to the proliferative stage of wound healing. Consequently, granulation tissue was increasingly formed. After three dressing changes, the proportion of non-granulating wounds fell from 54% to 12%. At the same time, the proportion of wounds with severe or complete granulation rose from 2% to 34% (Fig. 3). Building on the conditioning of the wound base, treatment with PermaFoam was able to lay the foundations for epithelisation. The mitosis and migration of the marginal epithelium can take place only on well-conditioned granulation tissue, allowing the ulcer to form replacement tissue. Whereas at the start of the trial 74% of wounds had formed no epithelial tissue, this was true in only 20% of cases with use of the foam dressing. At the end of the observational study, dense or even complete epithelisation was observed in more than one in four wounds (Fig. 4).

„The proportion of patients with severe pain fell from 40% to nearly 6% on PermaFoam."

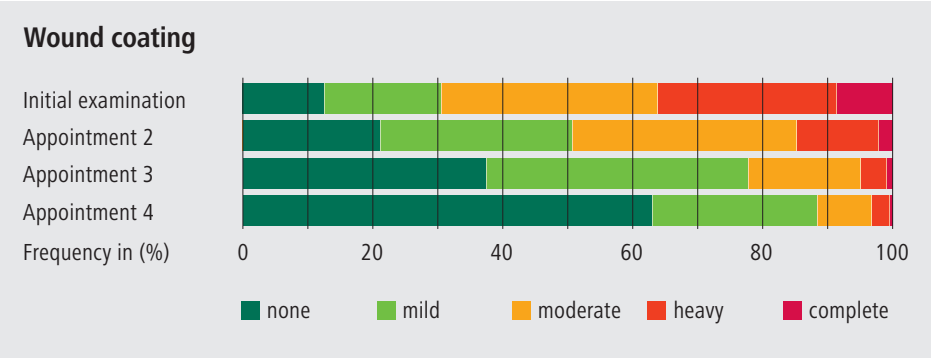

Fig. 2 Presence of wound coating: Treatment with PermaFoam reduced the proportion of completely coated wounds from 9% to 1%.

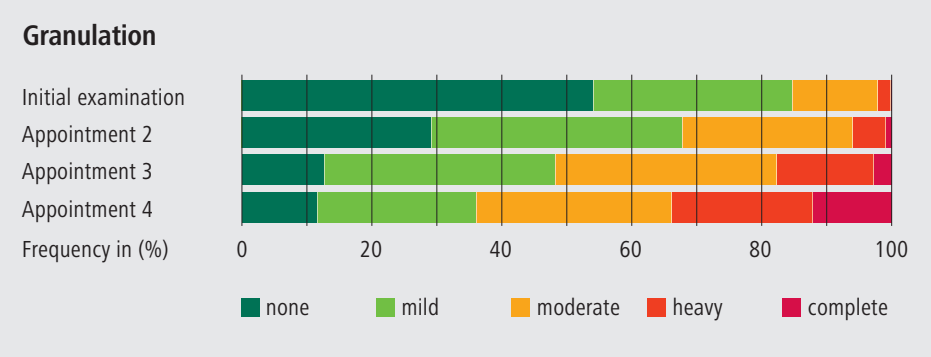

Fig. 3 Progress of granulation: At the start of treatment, only 2% of wounds were densely granulated, compared with more than one in five at the end.

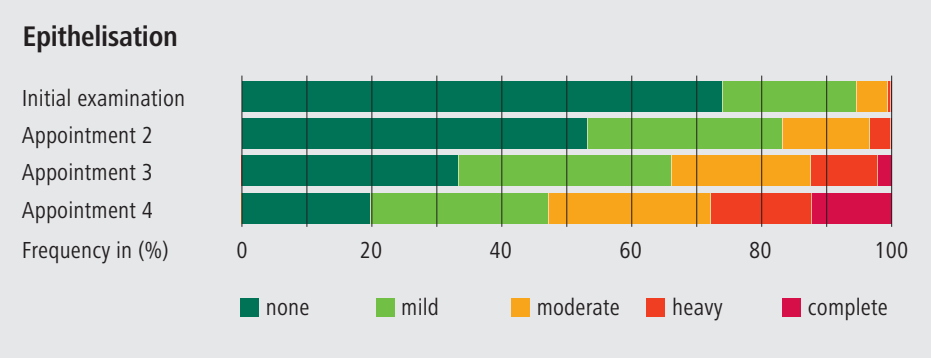

Fig. 4 Progress of epithelisation: The proportion of the wounds without epithelial tissue fell from 74% to 20% on PermaFoam.

Due to the effective cleansing and conditioning of the wound base, and the resultant encouragement of the wound-healing process, far fewer patients complained of wound pain during treatment with PermaFoam. Whereas at the start of the treatment 40% of patients had reported severe or very severe wound pain, this was still true in just under 6% of cases after the fourth appointment. At the same time, the proportion of patients with no or only mild pain rose from 31% to nearly 80% (Fig. 5).

Therefore, the physicians were able to see the positive effect of the foam dressing on the wound-healing process from the increasingly diminishing wound dimensions. The average wound size decreased by more than one-third.

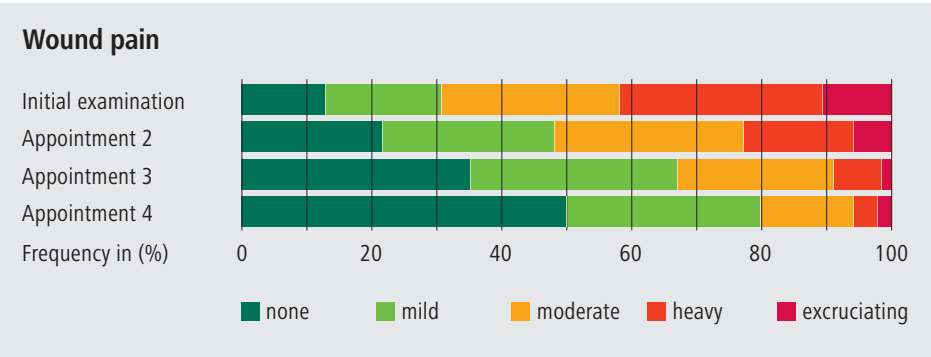

Fig. 5 Presence of wound pain: Before treatment, one in three patients had complained of severe or excruciating pain, compared with only 4% at the end of the treatment period.

Less irritation at the wound site

Excessive wound exudate and coating do not only interfere with the wound-healing process. They can also lead to maceration, oedema and considerable damage to the wound margins. Elderly patients, whose skin is often very sensitive due to age-related changes and functional losses, are particularly at risk. Because of its absorption and retention capacity as well as the softness and elasticity of the material, the foam dressing does not only reduce the frequency of maceration (from 14% to 6%). The wound site as a whole benefits from the treatment: whereas at the initial examination only 5% of margins were unremarkable, this proportion rose to 40% during the course of the treatment (Tab. 1).

Physicians and patients were very satisfied with the wound treatment

The good clinical efficacy of the foam dressing is reflected in the way the treating physicians rated the product. Between 80% and 90% of the physicians rated the absorption capacity, wound cleansing, granulation-promoting effect, protection from maceration, tolerability to the skin, ease of handling and removability of PermaFoam as very good or good (Fig. 6). When asked for their overall impression of wound treatment with PermaFoam, 85% gave scores of very good and good. One in ten physicians rated the product as satisfactory, 2% as adequate and 1.5% as deficient.

One in two physicians rated tolerability to the skin in the patients who were treated with the self-adhesive PermaFoam as very good and 40% as good. The positive evaluation of tolerability to the skin was connected with the "very good" and "good" removability (84%) and adhesion (90%) of the product.

Overall, one in five physicians considered that their expectations of wound treatment with PermaFoam had been exceeded and one in two that they had been met. Only just under one in ten considered their expectations to have "not really" or "not" been met.

Tab. 1: Condition of the wound site at initial examination and at final examination in %

	Initial examination	Final examination
Unremarkable	5	40
Oedema	17	9
Maceration	14	6
Warmth	12	5
Eczema	11	8
Hyperkeratosis	5	4
Redness	36	28

The patients treated rated the foam dressing as positively as did the physicians. Over 90% rated the wearing comfort as well as the tolerance of PermaFoam as very good or good. As regards overall impression, 44% rated the foam dressing as very good, 43% as good.

How effective was PermaFoam under compression therapy?

As previous laboratory tests had already shown, PermaFoam retains its high absorption capacity even under compressive forces of the magnitude produced by a class III compression stocking (42 mm Hg). In this situation, the foam dressing loses only 12% of its original absorption capacity. This is why PermaFoam is also effective in patients receiving compression treatment in addition to wound treatment. In the trial, this was confirmed in the 444 patients who were receiving concomitant compression treatment for chronic venous incompetence because of their venous leg ulcer (Ulcus cruris venosum) or arterial-venous leg ulcer (Ulcus cruris mixtum). Almost 92% of the treating physicians were of the opinion that the foam dressing was very well-suited or well-suited for use in association with compression treatment (Fig. 7).

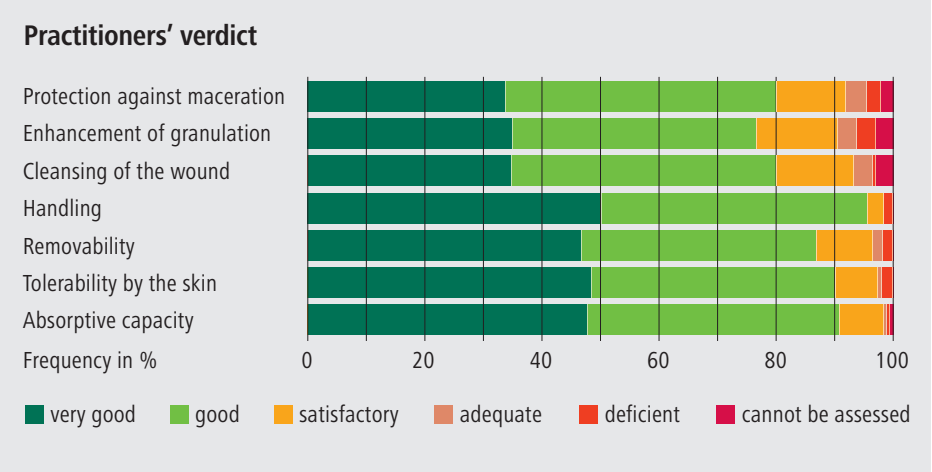

Fig. 6 Assessment of PermaFoam by the treating physician. Both the effect and tolerance were rated as very good or good by over 80% of the physicians.

When used in association with compression treatment, the physicians principally used PermaFoam without an adhesive edge. Since many leg ulcer patients (Ulcus cruris) have very sensitive and in some cases already damaged skin around the wound, even a skin-compatible adhesive could precipitate further skin irritation as a result of the permanent pressure.

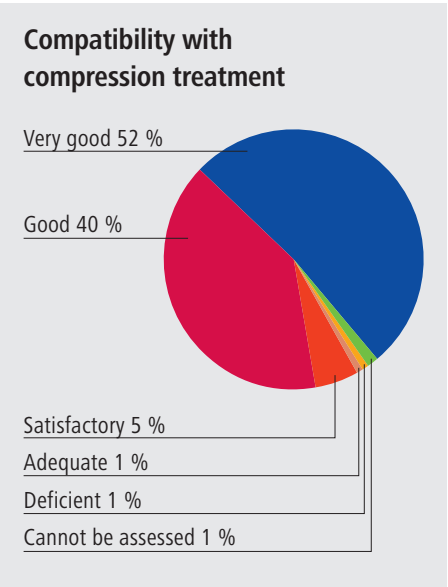

Fig. 7 PermaFoam in combination with compression treatment. More than 90% of the physicians were of the opinion that PermaFoam has a very good or good effect if it is used under concomitant compression treatment.

Conclusion

The good efficacy of PermaFoam had already been demonstrated in product tests. The foregoing observational study in over 800 patients now confirms the effectiveness of the foam dressing in everyday practice. Despite a large number of very old, mostly multimorbid patients, the majority of whom had chronic, poorly healing wounds, PermaFoam conditioned the wound base effectively and quickly encouraged florid granulation. The new foam structure facilitates a stronger capillary effect and an increased ability to absorb viscous cellular detritus and pus, because the larger pores on the wound-facing side do not become blocked prematurely. This means that the dressing can be left on the wound for several days – even in cases of relatively heavy exudation. ■

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