The clinical performance of PermaFoam cavity in the management of chronic wounds: a prospective, non-randomized clinical observation study

Summary

In the treatment of patients with chronic wounds, polyurethane foam dressings provide a moist wound environment while, at the same time, absorbing excessive amounts of exudate and debris from the wound.

Clinical efficacy as well as the tolerance of the foam dressing PermaFoam cavity was assessed in a prospective, non-randomized, non-comparative, open-label study. 15 centers recruited 57 outpatients with delayed/non-healing wounds of different etiologies. At the beginning of treatment and after 3 dressing changes, the physicians quantified the clinical appearance of the wound, peri-wound skin site and patient-reported pain.

At the beginning of the study, an average of 54% of the wound surface was covered with slough, granulation tissue was apparent in 41%, and 4% showed epithelialization. After 3 dressing changes, the relative proportion had shifted to 29% for slough, 59% for granulation tissue and 11% for epithelialization, respectively. Furthermore, treatment with PermaFoam cavity reduced the extent of exudation, intensity of patient-reported pain and irritations of the perilesional skin.

This study provides interesting results of the initial evidence for the clinical performance of PermaFoam cavity. By providing a moist wound environment and an effective management of excessive exudate, PermaFoam cavity stimulates the formation of granulation and epithelialization, while protecting the surrounding skin.

Introduction

Treatment of patients with chronic wounds involves – besides treating the underlying disease – the stage-adapted use of hydroactive wound dressings (1). By maintaining moist wound conditions, hydroactive dressings, e.g. hydrogels, polyurethane foams or alginates, encourage the migration of key cells, such as macrophages, keratinocytes, fibroblasts and endothelial cells, which ultimately encourage granulation and reepithelialization (2). However, excessive wound fluid burdened with excessive protease levels interferes with wound healing, and inappropriate control of exudates from chronic wounds can lead to significant clinical problems, such as maceration of the surrounding skin, involving skin breakdown, wound enlargement and increased pain (3). On the other hand, if a wound is kept too dry, the healing process is delayed, and dressing changes are much more painful due to adhesion of the dressing material to the wound bed (4). To achieve the right balance of moisture it is important to apply a phase-adapted, adequate hydroactive wound dressing to support the wound-healing process (5). An appropriate wound dressing can remove excessive amounts of wound exudates while retaining a moist environment that supports the healing process (4, 6). Polyurethane foam dressings have been introduced into clinical practise in order to promote a moist wound environment while, at the same time, being able to absorb excessive amounts of exudate and debris from the wound (7).

PermaFoam cavity has been developed for deep, cavernous wounds. This polyurethane foam dressing absorbs excessive exudates and creates a moist wound environment that stimulates wound healing. PermaFoam cavity is suitable for the treatment of medium to heavily exuding, deep, fissured wounds. As a folded tamponade, it is especially suited for packing wound cavities and deep ulcers, which present a frequent problem in wound management. The fluid-handling and absorbance capacity of the foam dressing PermaFoam cavity has been proved in laboratory investigations.

The clinical efficacy, its potential for supporting wound healing as well as the tolerance of the dressing is the subject of the present prospective clinical observational study. The study analyzes the clinical performance of the new PermaFoam cavity dressing in an unselected panel of patients, mostly reflecting non-healing wounds of different aetiologies encountered in daily practice.

Material and method

The clinical performance of PermaFoam cavity was assessed in a prospective, non-randomized, non-comparative, open-label observational study. The CE-certified foam dressing was used in this study in line with its intended use as recommended by the manufacturer.

15 medical centers (7 physicians, 8 community nursing services) recruited 57 outpatients with delayed/non-healing wounds of different etiologies. Using a standardized questionnaire at the beginning of the study, the patients' age, sex, type and duration of the wound, prior treatment, physical condition and concomitant medication were recorded. At the beginning and after 3 dressing changes, the attending physicians quantified the clinical appearance of the wound by ascribing a score for slough/eschar, granulation and epithelialization. Further wound parameters like exudation level (determined using a four-point scale: none, sparse, moderate, heavy), peri-wound skin site and pain (none, mild, moderate, strong) were also assessed.

Dressings were changed as clinically indicated by the medical staff every 3 days on average. The average total treatment time was 9 days. Overall, 169 dressing changes were documented. In one patient, PermaFoam cavity had been changed only twice; one patient died after the first changing.

At the end of the observational study physicians and nursing staff evaluated the clinical product performance, particularly its tolerance by patients. In addition, patients were asked about the tolerance and the wearing comfort of PermaFoam cavity at the end of the study.

Table 1: Etiologies of the wounds (multiple nominations possible)

Pressure sores	16
Wound-healing delays (postoperative, metabolic)	15
Other	9
Mixed ulcers	8
Venous leg ulcers	6
Pressure sores due to Diabetes Mellitus	6
Peripheral neuropathy	5
Sinus pilonidalis	4
Tumour wounds	4
Acute wounds (traumatic)	2
Diabetic gangrenes	2

Statistical analysis

This was a non-randomized, non-comparative study, descriptive statistical analyses were performed. Data summaries were prepared for all parameters using percentages. Thus, base-

line characteristics and assessments of wound parameters as well as a final evaluation by physicians and patients were summarized.

Results

Patient characteristics

Overall, 23 men and 34 women with a mean age of 69 (±16) years were enrolled in this study. The majority of the patients suffered from chronic, non/delayed healing wounds. Most frequently PermaFoam cavity was used for the treatment of pressure sores (16 patients), venous or mixed ulcers (14 patients) and delayed postoperative wound-healing (12 patients). Patient demographics, and wound characteristics are listed in table 1 and 2.

Table 2: Patient demographics and wound characteristics

Age, mean (SD)	69 years (±16 years)
Female	60%
Male	40%
Treatment duration	9 days ± 5.5 days
Wound duration	1.4 years (± 4.1 years) (median 2 months)
Wound size on admittance	5.5 ± 4 x 3.6 ± 3 cm, depth 16.4 cm
Wound size at the end of treatment	5.2 ± 3.9 x 3.4 ± 3 cm, depth 14.5 cm

About 68% of the patients were in very good physical condition, or their condition was consistent with age, respectively. Due to comorbid conditions, only 32% were in a debilitated state of health according to their treating physicians. 48% of the patients received concomitant drug treatment such as anticoagulants, antidiabetics, antibiotics or antihypertensives.

Patients had suffered from these wounds for an average of 1.4 years. Overall, 25 wounds had cavities. Of the 57 patients treated, 46 had undergone prior treatment with other modern wound dressing. A total of 36 different products had been used. Most frequently patients had been previously treated with antiseptic-containing gauzes, alginates, hydrogels, laminate compresses and foam dressings.

Concomitant to PermaFoam cavity treatment, 54 patients received adjunctive treatment: Treating physicians applied compression therapy to 14 patients. In 26 patients pressure relief by special mattresses or pressure relieving shoes further supported the wound healing process. Other concomitant treatment included nutritional support (6 patients), antibiosis (3), varicose vein surgery and physiotherapy (1).

For secondary wound coverage, 11 different products were used in the course of this study. The physicians mostly used gauze swabs (60%), foam dressings (20%) and wound dressing pads (7%).

Table 3: Reasons for including patients into the observational study (multiple nominations possible)

	[%]
First wound treatment	26.3
Treatment of recurrent wound	7.0
Chronic wound	49.1
Intolerance of prior therapy	3.5
Failure of prior therapy	22.8

Physicians stated different reasons for enrolling their patients into the study (table 3). One in two physicians gave as the main reason that they wanted to effectively treat a chronic, poorly healing wound. One in four mentioned that prior therapy had not been successful or patients were dissatisfied with previous therapies. For 26.3% the treatment with PermaFoam cavity had been the first treatment of the wound.

Wound-healing process

At the beginning of the study, an average of 54% of the wound surface was covered with slough, granulation tissue was apparent in 41%, and 4% showed epithelialization. After 3 dressing changes, the relative proportion had shifted to 29% for slough, 59% for granulation tissue and 11% for epithelialization, respectively (fig. 1). Similarly, characteristics of slough altered, with necrotic slough decreasing from 23% to 5% at the end of the study. In addition, treatment with PermaFoam cavity reduced the extent of exudation in the course of the study. At the beginning, physicians assessed 32% of the wounds as strongly exuding, whereas 23% exuded minimally. By the end of the observation period, only 11% of the wounds still showed strong exudation, whereas the proportion of minimally exuding wounds had increased to 40% (fig. 2). In 2 patients an accumulation of exudate was observed in the folds of the foam dressing, one of these patients showed exceptionally strong exudation. The quantity of wounds with cavities declined from 25 to 18.

Patient-reported strong or moderate pain sensation during dressing changes decreased from 45% to 26% during the course of the study. At the same time, the number of patients without pain sensation increased from 21% to 33% (fig. 3). In parallel to reported lower pain levels analgesic drug treatment had been reduced. At the beginning of the study, more than 17% of the patients had taken analgesics because of permanent wound pain or pain during dressing changes. After treatment with PermaFoam cavity this was reduced to 11%.

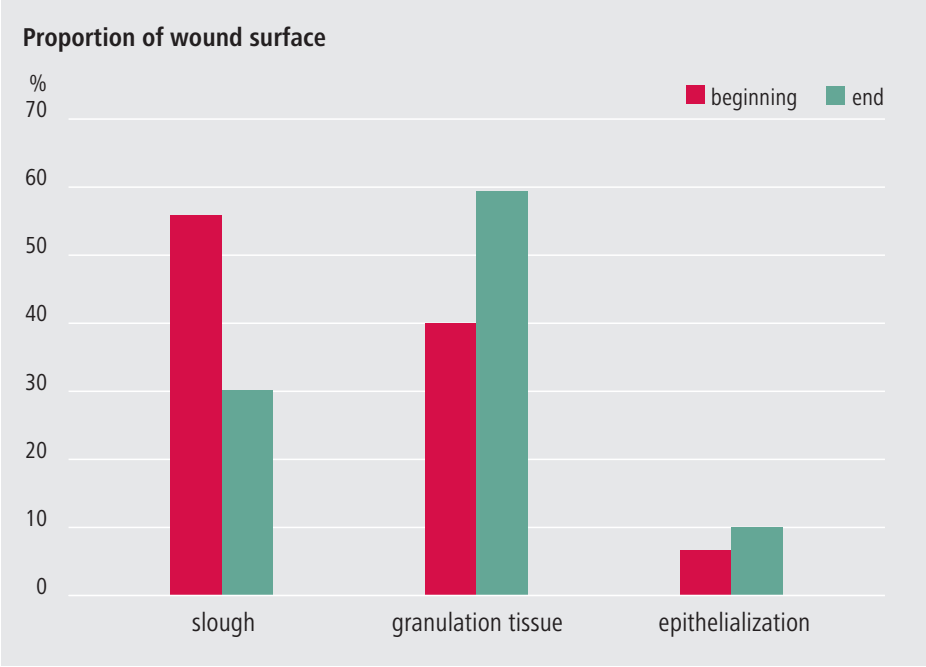


Fig. 1: Evaluation of wound appearance after treatment with PermaFoam cavity. Wounds of different aetiologies were treated with PermaFoam cavity, with 3 consecutive dressing changes being made. Subjective evaluation was recorded at each dressing change, and the results are shown as difference comparing beginning and end of the study.

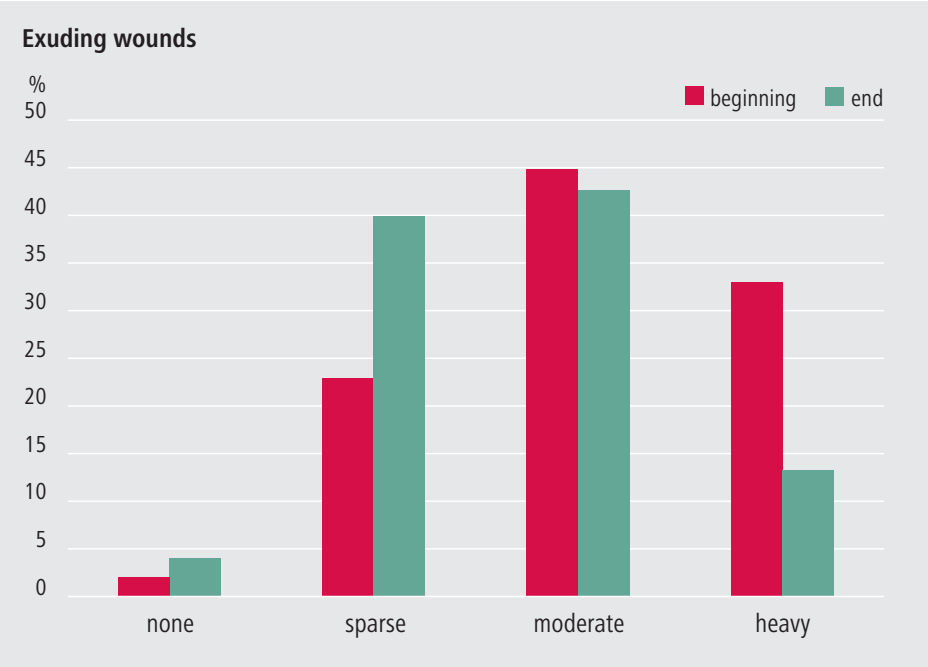


Fig. 2: Exudation before and after treatment with PermaFoam cavity.

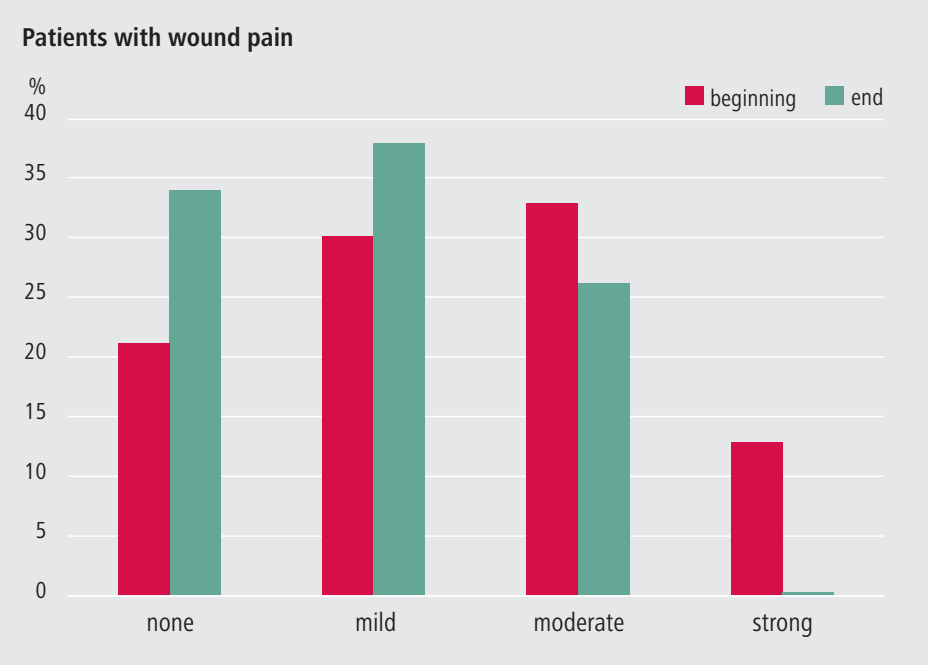


Fig 3: Presence of wound pain at the beginning and end of the observational period.

Perilesional skin

During wound treatment with PermaFoam cavity physicians diagnosed less irritation of the perilesional skin. At the beginning, 49% of the patients had a surrounding skin without pathological findings. During the observational period this increased to 67%. Especially symptoms like oedema, (from 17.5% to 7%), macerations (from 10.5% to 3.5%) and hyperthermia (from 16% to 7%) were meliorated (table 4).

Subjective evaluation by physicians and patients

Between 80% and 90% of the physicians rated the product's absorption capacity, its wound cleansing effect, tolerability by patients, ease of product handling, contact to wound surface, formability and the removableness of PermaFoam cavity as very good or good. When asked for their overall judgement of the effects of the foam dressing on wound healing, more than 90% of physicians gave scores of very good and good. More than 85% of the physicians judged that, in comparison with the initial examination, the condition of the wounds had improved (fig. 4).

Patients rated the foam dressing as positively as did the physicians. Between 80% and 85% rated the wearing comfort as well as the tolerance of PermaFoam cavity during dressing changes as very good or good. Overall impression of PermaFoam cavity treatment was rated as very good by 39% and as good by 44%.

Discussion

The good clinical performance of PermaFoam cavity in this study suggests that the foam dressing is appropriate for treating heavily to moderately exuding chronic wounds. Owing to their absorption and retention capacity, polyurethane foam dressings maintain a balance between moisture and exudates management and therefore support wound healing (7, 8). Furthermore, the observational study substantiates an excellent tolerance of PermaFoam cavity by patients as well as good handling properties for physicians and nursing staff. Our small non-randomized and non-comparative clinical observational trial can only give some fist information about the efficacy and tolerance of the treatment with PermaFoam cavity. 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 wounds encountered in daily practice.

Most patients in this study suffered from chronic, non-healing wounds. The condition of the wound base and the surrounding skin at the time of inclusion into the study were correspondingly poor. More than the half of the wound area was covered with slough, 41% with granulation tissue. Only 4% showed epithelial tissue. At the same time one in three wounds exuded heavily. It is reported that excessive exudate causes the degradation of extracellular matrix proteins and growth factors, prolongs inflammation, interferes with cell proliferation and eventually leads to the breakdown of the vulnerable granulation tissue (9, 10). Therefore, an effective exudate management with the absorption of excessive wound fluid, while still providing a moist environment, is important for the healing process of poorly healing wounds (11). PermaFoam cavity absorbed and compartmentalized the excessive wound exudate, effectively cleansing the wound. Clinically the wounds clearly improved during the observational study. Slough reduced and granulation tissue increasingly built up, providing a well-conditioned wound base for reepithelialization and reducing the size of the wounds.

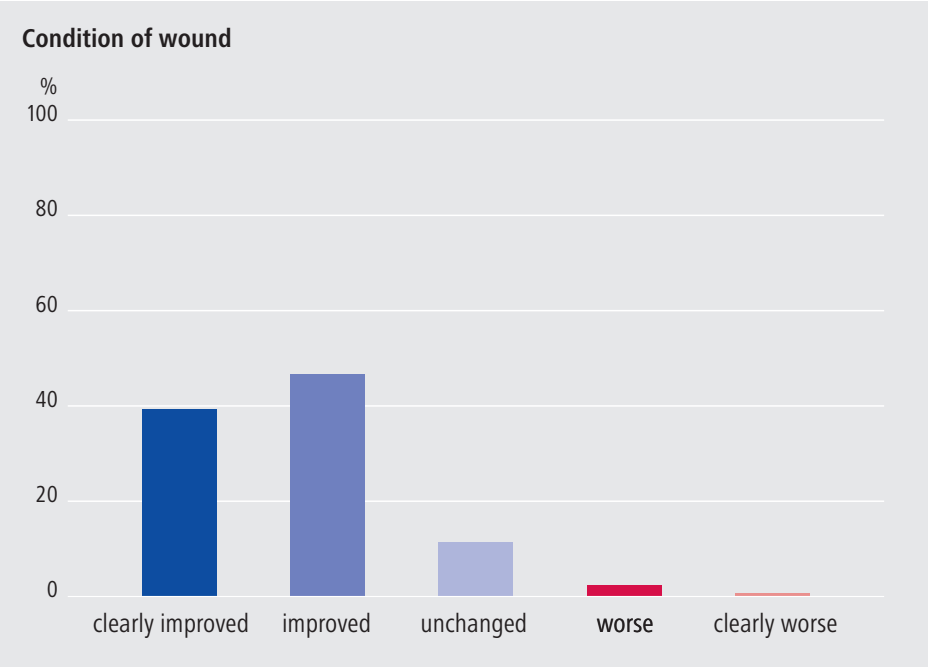
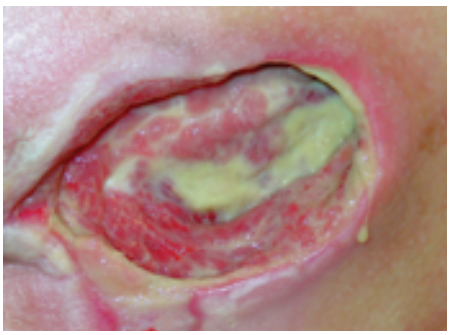
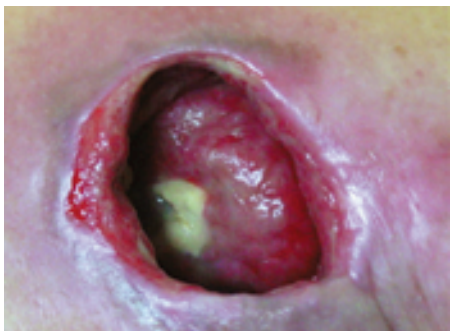


Fig. 4: Condition of wound after treatment with PermaFoam cavity, compared to beginning of study (evaluation by physicians).

Table 4: Development of clinical symptoms of the wound surrounding skin in the course of the study

Wound surrounding skin	Start of the observational study [%]	First dressing change [%]	Second dressing change [%]	End of the observational study [%]
Without pathological findings	49.1	52.6	57.9	66.7
Oedema	17.5	12.3	10.5	7.0
Erythema	21.1	22.8	17.5	14.0
Hyperthermia	15.8	14.0	8.8	7.0
Macerations	10.5	7.0	5.3	3.5
Eczema	3.5	3.5	1.8	1.8
Hyperkeratosis	10.5	7.0	7.0	7.0
Infections	3.5	3.5	0.0	1.8
Others (e.g. dry, scaly skin)	5.3	1.8	1.8	3.5





Case study:
70 year old female patient with a bedsore
The patient was in a debilitated state of health and suffered from the decubitus ulcer (stage III) for three months. Before the commencement of the treatment, 40% of the wound bed was covered with coatings, granulation tissue was apparent in 60% (left). Furthermore, the physician assessed the wound as strongly exuding. For removing slough and reducing exudation, the patient was treated with PermaFoam cavity. Gauze was used as a secondary dressing. Two days later, after the first dressing change, the percentage of the wound surface with slough has markedly decreased (right). After two more dressing changes and a total treatment time of 5 days, only 10% of the ulcer was still covered with slough, 80% with granulation. 10% of the wound bed was re-epithelialized. At the same time the extent of exudation was markedly reduced, the wound exuded only minimally.

The skin surrounding of non-healing ulcers is sensitive and prone to macerations, erythema, oedema and erosions due to excessive wound exudate. Especially elderly people, whose skin is often very sensitive due to age-related changes are particularly at risk (reviewed in 12). Dressings should protect the surrounding skin from excessive exudate. This observational study suggests that patients treated with PermaFoam cavity benefited showing a lower frequency of maceration and oedema. Perilesional skin improved from 49% of patients with normal skin to nearly 67% at the end of the study. To a large extent may this result from the compartmentalization of excessive wound fluid within the PermaFoam cavity dressing. Exudate management by PermaFoam was judged as very good or good by more than 80% of the examining doctors.

Many patients with chronic wounds suffer pain that causes distress and therefore has a huge impact on quality of life (13, 14). Dressing removal is considered to be the most painful procedure apart from sharp debridement for most patients. To prevent painful dressing changes, design and dressing materials have been optimized to be less traumatic, i.e. dressings that do not stick to the wound should be chosen (15). In our study PermaFoam cavity treatment resulted in far fewer patients complaining of wound pain. Softness and easy handling properties appear to have contributed to this patient reported improvement. Furthermore, wound fluid handling characteristics seem to be well balanced as an absorbing of too much fluid would be associated with an adherence of the dressing to the wound bed. A direct consequence of this could lead to an accidental traumatic removal and pain. Creating and maintaining a sufficiently moist environment is, therefore, important with regard to reducing persistent wound pain (4).

Conclusions

This was a non-randomized, non-comparative trial in an unselected panel of 57 patients with mostly non-healing chronic wounds. The study provides interesting initial evidence of the clinical performance of PermaFoam cavity. By providing a moist wound environment and an effective management of excessive exudate, PermaFoam cavity stimulated the formation of granulation and epithelialisation, while protecting the surrounding skin.

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