Clinical efficacy of foam dressing PermaFoam in the treatment of chronic wounds – a multicentre observational study with 53 patients

Modified version of the Spanish publication: Eficacia de PermaFoam en el tratamiento de úlceras crónicas. Revista de Enfermería ROL 2005; 28: 29–34.
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Background: The treatment of wounds with polyurethane foam dressings has been reported to promote a moist wound environment while, at the same time, being able to absorb excessive amounts of exudate and debris from the wound.
Objective: The clinical performance of the foam dressing PermaFoam in the treatment of chronic wounds was evaluated in a prospective and multicentre observational study.
Method: 53 patients (mean age 76 years) with 56 chronic wounds of various aetiologies were enrolled. The study was conducted over a maximum of 8 weeks of treatment.
Results: In the course of the study, 21 wounds (37.5%) completely healed; overall the absolute average surface reduction was 13.42 cm^2 (CI 95%: 7.39-19.45), the mean relative reduction of wound size was 61.3% (CI 95%: 50.66-71.97). Complete wound healing or a reduction of wound size could be observed regardless of aetiology, stage or duration of wound. Furthermore, treatment with PermaFoam improved levels of exudation and irritations of the perilesional skin.
Conclusion: The findings reported in this study suggest that PermaFoam stimulates the formation of granulation and epithelialisation by providing a balanced moist wound environment. The state of all wounds treated improved regardless of their aetiology, state, or length of presence.

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 encourage the migration of key cells, such as macrophages, keratinocytes, fibroblasts and endothelial cells, which ultimately encourage granulation and reepithelialisation (2). 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 (3). An appropriate wound dressing can remove excessive amounts of wound exudate while retaining a moist environment that supports the healing process (4, 5).

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. The family of polyurethane foams covers a whole series of dressings with similar properties, but the physical structures may be different. When choosing a dressing for the treatment of any wound, its characteristics and performance must be taken into account. The fluid absorption and retention capacity of PermaFoam has been investigated in laboratory tests. Due to the high affinity of the foam material for exudate, PermaFoam binds it very efficiently. In comparison to competitor products, PermaFoam showed the highest residual absorption capacity (page 5).

The study of Fernando Martinez Cuervo and his colleagues, which was published in the Spanish journal Rev Rol Enf 2005; 28: 29–34, assessed the clinical efficacy of the polyurethane foam dressing PermaFoam in the treatment of chronic wounds of various aetiologies. The secondary objective was to evaluate the ease of use and application.

Material and methods

53 patients were enrolled in the prospective multicentre observational study. All patients had to be 18 years or older. Exclusion criteria are listed in table 1. Using a standardised questionnaire the attending physicians recorded following study variables: demographic characteristics (age; sex; centre); clinical examination of the patient (concurrent diseases; consumption of medications; nutritional supplements); initial description of the ulcer (aetiology; duration; diameters; stage; localisation; exudate and state of perilesional skin); clinical outcome of the ulcer (recording of variations from the initial description; changes of dressing; and reasons for change); and the opinion of the professionals about the product.

The maximum duration of the study was 8 weeks for each patient, unless their wounds healed earlier or they withdrew. Re-assessments of wound state were performed during the 1st, 3rd, 5th and 7th week, and the final clinical examination was undertaken in the 8th week.

Table 1: Exclusion criteria

Ulcers stage I
First or third degree burns
Acute wounds
Dry eschars or ulcers
Patients with sepsis/bacteraemia
Cellulitis or osteomyelitis
Terminal patients
Patients receiving treatment with corticosteroids
Known hypersensitivity to PermaFoam dressings or to any of its materials

The CE-certified foam dressing was used in this study in line with its intended use as recommended by the manufacturer. PermaFoam was applied to the wounds, using a size which overlapped the margins of the wound by at least 2–3 centimetres to encourage its adaptation and prevent rapid detachment.

Statistical analysis

The information recorded was processed in a database and analysed by the SPSS statistical programme (V.12.0). Descriptive statistics of all the variables were computed. The qualitative variables were presented as frequencies and proportions, and for the quantitative variables indices of central tendency were also reported. The statistical significance of the qualitative data was determined by χ^2-tests. To confirm whether there were any significant changes during the study period in terms of healing, a repeated measures analysis of variance (repeated measures ANOVA) was performed for the whole wound group and compared for duration and aetiology.

Results

Patients' characteristics

Of the 53 patients 31 (58%) were women and 22 (42%) men (table 2). The participants had a mean age of 76.1 years (±13.2 years, range 42 to 99 years). Patient suffered from following comorbidities: diabetes in 13 patients (23%), malnutrition in 12 (21%) and lower limb arteriopathy in 11 (20%). 37 patients were taking two or more drugs (70%), the most frequent being anxiolytics, neuroleptics, hypnotics, anticoagulants and antihypertensives.

Table 2: Patient demographics

Age, mean (SD, range)	76.1 years (±13.18 years, 42 to 99 years)
Female	58%
Male	42%

Table 3: Aetiologies of the wounds (n = 56)

Pressure sores	26
Venous ulcers	11
Mixed lesions	10
Surgical wounds	4
Burns	3
Neutrotrophic wound	1
Traumatic wound	1

The majority of the patients suffered from chronic, non/delayed healing wounds (table 3). Overall, 56 wounds were treated with a mean dressing change every 3 days. The mean wound duration was 270 days (±604 days), the median 85 days and the mode 365 days.

Wound healing

Overall, 21 wounds (37.5%) completely healed in the course of the study. 6 patients withdrew (4 due to transfer and 2 because of a fatal outcome unrelated to the treatment). The mean initial size of the wounds was 26.44 cm^2 (± 40.04 cm^2) (table 4) and at the end of the study the mean absolute reduction was 13.42 cm^2 (95% CI: 7.39-19.45), the mean relative reduction 61.31% (95% CI: 50.66-71.97).

The wound healing rate expressed as the percentage relative reduction of the wound size (and understood as the mean percentage wound healed), is summarised in figure 1. This graph illustrates the mean percentage relative reduction in the size of the wounds over time. Figure 2 depicts the time course of healing in the same terms as figure 1, but divided into two groups according to the duration of the lesions with a duration less than (group 1) and those with a duration greater than (group 2) 85 days (85 days was the median duration of all lesions). Finally, figure 3 depicts the time course of the relative percentage reduction of the lesions according to their aetiology.

Exudation and perilesional skin

At the beginning of the study, 36 wounds exhibited a moderate, 17 a heavy and 3 a very heavy exudation. Of the wounds, which had not healed after eight weeks, 9 showed a sparse, 15 moderate, 4 heavy and 1 very heavy exudation (table 5).

At the beginning of the treatment with PermaFoam, 29 of the 56 chronic wounds displayed pathological diagnosis in the perilesional skin (12 maceration, 9 erytheme, 4

Table 4: Wound characteristics (n = 56)

Wound duration (SD, median)	270 days (± 604 days, 85 days)
Wound size at admittance (SD)	26.44 cm^2 (± 40.04 cm^2)
Wound size at the end of treatment	13.02 cm^2
Absolute reduction	13.42 cm^2 (95% CI: 7.39-19.45)
Relative reduction	61.31% (95% CI: 50.66-71.97)

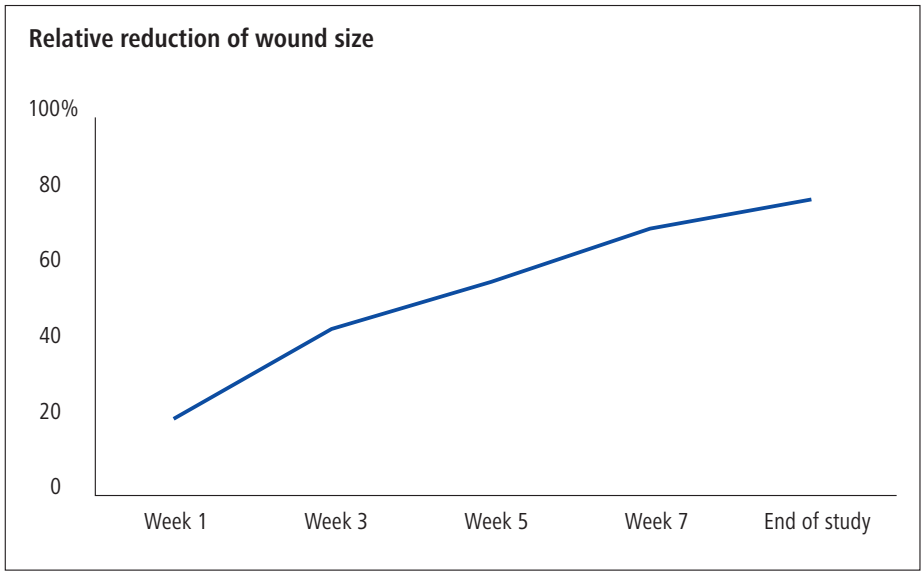

Figure 1 Relative reduction of wound size in the course of the study, n = 56 ($p < 0.001$)

were lacerated and 4 characterised as others). At the end of the study, in 5 wounds perilesional disorders could be diagnosed: 3 wound had an erythematous skin, 1 wound macerated and 1 wound both macerated and showed erythematous tissue (table 6). The opinion of the professionals on the dressing and its performance is given in figure 4.

Discussion

The foam dressing PermaFoam demonstrated a very good performance profile in the course of the study. In an unselected panel of patients, mostly reflecting non-healing wounds encountered in daily practice, the wound size clearly decreased. The long mean wound duration shows that physicians were confronted with long-term wounds, which have undergone multiple treatments and multiple medications. The positive assessment by the treating physicians indicates that PermaFoam was beneficial. The condition of the wound base (slough, exudation) and the surrounding skin at the time of inclusion into the study were correspondingly poor.

The repeated measures ANOVA depicts a constant trend in all the accompanying figures (in general terms figures 1 and 2). This trend indicates a significant reduction in the size of the wound over the study period, but which is not affected either by the duration of the wounds or their aetiology. 11 lesions (20%) were venous ulcers to which compression measures were not applied (a basic pillar in their treatment), thus increasing the difficulty of healing (6). Despite this, 2 venous ulcers (3.5% of the total or 18% of venous ulcers) healed without the application of compression therapy.

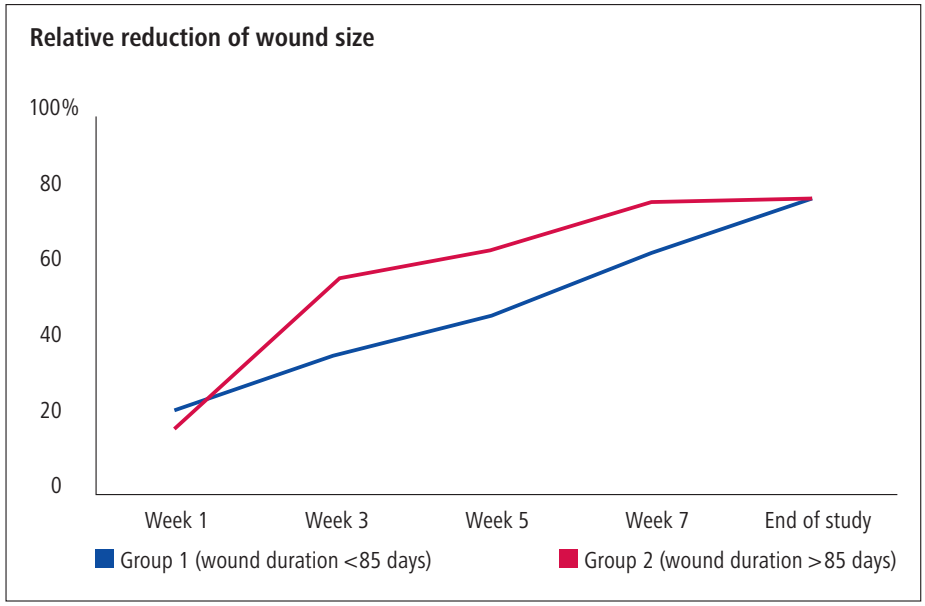

Figure 2 Relative reduction of wound size according to the duration of the wound, n = 56 ($p < 0.001$ for time course; p = not significant for comparison of curves)

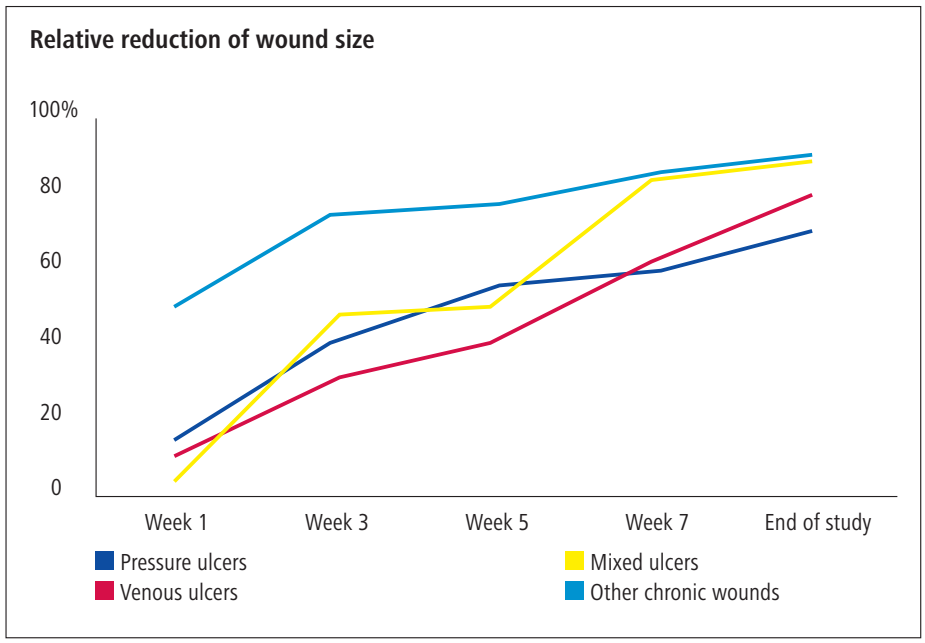

Figure 3 Relative reduction of wound size according to the aetiology, n = 56 ($p < 0.001$ for time course; p = not significant for comparison by groups)

During the study we discovered that wounds which did not respond to previous treatments entered into a sustained healing process and that the activity of the cells in the bed and at the borders was maintained without becoming senescent. Cell ageing is considered by Falanga (7) to be a genuine problem of chronic wounds.

Maceration is usually the most common problem of the perilesional area (8), sometimes as a result of the use of moist wound dressings (9). Another common problem of the perilesional skin is erythema, which is usually caused due to the presence of exudate or the reaction between the skin and the adhesives in the dressings (10, 11). In the study of Cuervo and colleagues appropriate monitoring of the exudate together with the characteristics of the adhesives has resulted in a smaller proportion of maceration and erythema of the perilesional skin.

Maintaining adequate moisture conditions in the wound bed and sparing the perilesional skin is one of the cardinal rules of the Agency for Health Care Policy and Research (12) in the treatment of chronic wounds. The study dressing promoted control of the exudate and care of the perilesional skin.

The mean retention time for this type of dressing is 2 to 4 days, depending on the quantity of exudate and the characteristics of the lesion (13, 14, 15), although it can be maintained for up to a maximum of 7 days. In our study, the mean retention time was 2.74 days, in accordance with the available evidence, and we believe that the high number of lesions which were subject to systematic dressing-change routines (for example: Monday, Wednesday and Friday; 28% of changes of dressings) reduced the mean retention time.

Conclusions

The use of PermaFoam for the wounds under study occasioned the complete healing or improvement of the final size of all the lesions treated, regardless of aetiology, stage or du-

Table 5: Exudation (n = 56)

	at admittance	end of study (wounds without complete healing)
Sparse	0	9
Moderate	36	15
Heavy	17	4
Very heavy	3	1

Table 6: Perilesional skin

	at admittance	end of study
Maceration	12	2
Erythematous	9	3
Lacerated	4	0

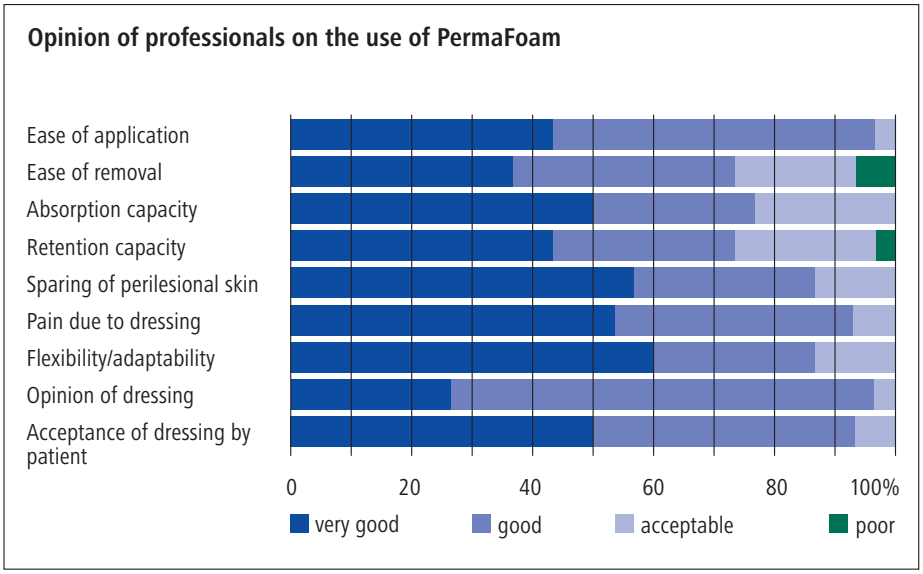

Figure 4 Assessment of wound treatment with PermaFoam by physicians

ration. The levels of exudate were controlled, the retention time on the lesion prolonged and the number of dressing changes reduced. It spares the perilesional skin and reduces changes in the perilesional area by eliminating the exudate from the surrounding skin. The assessment of the patients and professionals was good or very good for practically all the aspects evaluated.

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Composition and mode of action of PermaFoam

PermaFoam is composed of three layers (fig. 1):

1. Wicking layer: The wound facing side is characterised by large-sized pores (1000 µm diameter) which rapidly absorb large quantities of exudate, cell residues and viscous exudates without the pores collapsing or clogging.
2. Distribution layer: The second layer is composed of pores of smaller diameter (400–500 µm), which promotes good distribution and retention of the exudate absorbed.
3. Semipermeable top layer: The last layer is characterised by its pronounced elasticity and permeability to water vapour, endowing it with perfect adaptability and semipermeability.

This difference in pore size is known as pore gradient. The high affinity of the foam material efficiently holds exudate and cell residues, preventing exposure of the wound to aggressive proteolytic enzymes and reducing the risk of maceration. In a laboratory test PermaFoam showed the highest residual absorption capacity under pressure compared with four competitor foam dressings (fig. 2). For this reason PermaFoam is particularly efficient in combination with compression therapy.

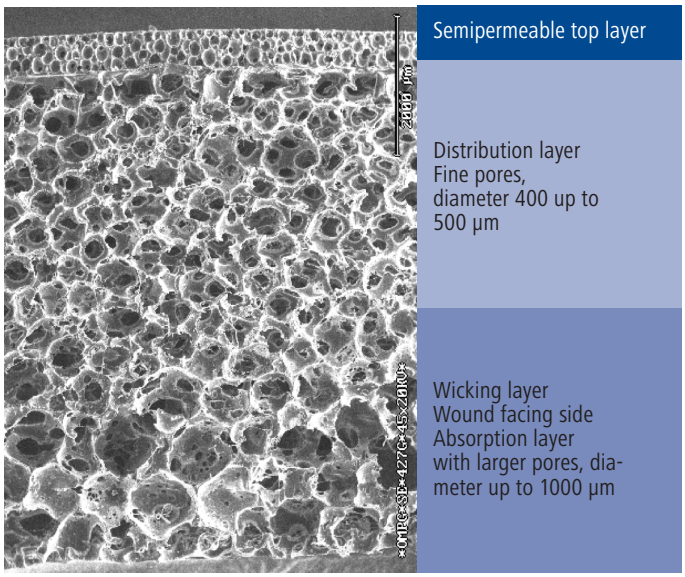

Figure 1: Pore size decreasing from the bottom (woundfacing side) to the top increases capillary strength, resulting in exudate absorption into foam matrix and the back.

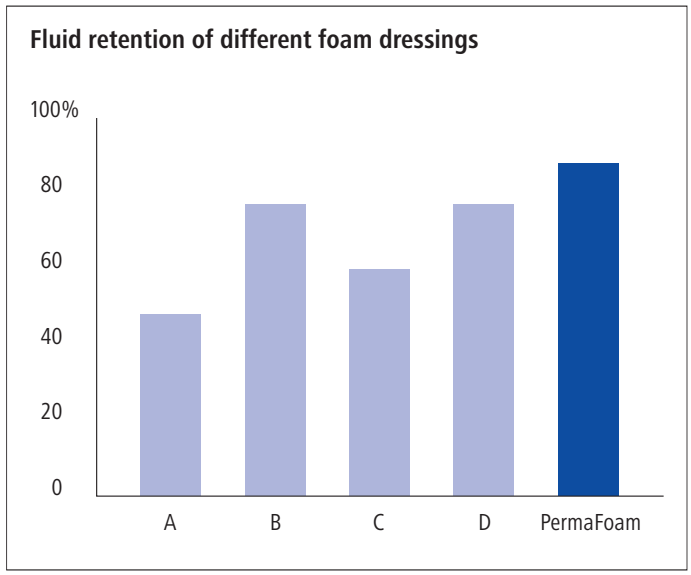

Figure 2: Comparison of residual absorption capacity (retention) of five foam dressings under a 35 mmHg pressure.

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