



# Clinical and Economic Impact of Wound Care Using a Polyurethane Foam Multilayer Dressing

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#### **ABSTRACT**

**OBJECTIVE:** To study the impact of a newly introduced dressing on efficiency and quality of care in routine clinical practice in a Spanish community setting. **DESIGN AND SETTING:** An ambispective multicenter observational study was conducted in 24 primary care centers and 6 nursing homes in 4 different Spanish regions. The study was carried out between November 2017 and March 2019. **PATIENTS AND INTERVENTION:** A total of 128 wounds in 94 patients (primary care, n = 79; nursing home, n = 15) were analyzed before and 4 weeks after switching to the study dressing.

**OUTCOME MEASURES:** Frequency of dressing changes; secondary outcomes were change in the mean wound area and weekly cost and patient and provider satisfaction.

**MAIN RESULTS:** The mean number of dressing changes was significantly reduced with the study dressing from  $3.14 \pm 1.77$  changes per week to  $1.66 \pm 0.87$  (P < .001), a 47.1% reduction in frequency. Wound area significantly reduced from  $9.90 \pm 19.62$  cm<sup>2</sup> to  $7.10 \pm 24.33$  cm<sup>2</sup>. In addition, a 58.7% reduction in weekly costs was achieved with the intervention. Patients and providers agreed that their satisfaction with wound care improved.

**CONCLUSIONS:** The use of the study dressing in routine clinical practice could lead to a major improvement in both efficiency and quality of wound care. Its use could reduce wound care-related costs through improvements in healing and a reduced frequency of dressing changes. It also enhanced the wound care experience from the perspective of both patients and providers.

**KEYWORDS:** care satisfaction, cost, dressing change, efficiency, healing, nursing home, primary care, wound care

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#### INTRODUCTION

In Spain, it is estimated that wound management accounts for approximately 5.2% of total healthcare costs. This represents a significant financial burden for the community services that treat the majority of wounds, and from a resource perspective, nurses spend more than 60% of their time on wound care. Accordingly, resource optimization is essential to improve the efficiency of care.

For example, the number and complexity of wound dressings available for healthcare professionals (HCPs) are on the rise, each one with their own set of features, and multiple dressings are often used in combination.<sup>3,4</sup> Because of this heterogeneity of existing products, providers and patients must be careful when selecting a dressing based on its use and performance characteristics.<sup>4</sup> Wet dressings (based on the principle of moist wound healing<sup>5</sup>) are more clinically effective and have a better cost-benefit ratio than traditional dressings.<sup>6</sup>

Further, although supplies and dressings represent 15% to 20% of costs in wound management, significant costs are also associated with other resources such as nursing time (30%–35% of total cost) and hospitalization (>50%).<sup>2,7</sup> Using dressings that reduce the need for cleansing, debridement, or ulcer assessment but are still clinically effective is key for efficiency.<sup>8,9</sup> More frequent dressing changes mean a greater number of patient care visits and increased cost for routine care.<sup>10,11</sup> Unnecessary dressing changes may have an impact on both patient

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well-being and resources.<sup>2</sup> Therefore, an important challenge for resource optimization is to develop dressings whose performance characteristics allow for a reduction in the number of dressing changes.

In addition, frequent removal and reapplication of dressings may delay wound healing <sup>10</sup> and a lack or excess of exudate can result in delayed healing and damage intact periwound skin. <sup>12,13</sup> Wound infection is associated with frequent dressing changes and increased exudate and can further inflate costs. <sup>2,14</sup> For these reasons, the ideal dressing should absorb and retain debris, bacteria, and exudate to maintain optimal moisture conditions and prevent infections. <sup>14</sup>

From a patient perspective, wounds have a significant impact on health, quality of life, and families. <sup>12,14,15</sup> Patients consider pain the most common and impactful symptom, leading to reduced mobility, sleep disorders, and employment difficulties. Other distressing symptoms include pruritus, discharge, and malodor. Patients may feel isolated, anxious, and stressed because of wound-related stigma, and this in turn can have a negative impact on the healing process. <sup>12,16</sup> Thus, factors such as a dressing's capacity to absorb exudate or ability to reduce pain and discomfort should be considered to ensure quality of care.

Recently, a multilayered hydrocellular polyurethane foam dressing (ALLEVYN Life; Smith + Nephew, Hull, UK) has been made available for use in clinical practice. This dressing promotes wound healing by reducing leakage via its highly absorbent core that allows for exudate retention. It incorporates a change indicator to guide dressing change frequency and masks exudate to enhance patient adherence to treatment and limit the social impact of wounds. This dressing may also prevent infection through a barrier function that blocks liquids and bacteria. The dressing is easy to lift and remove without pain, protecting the skin against trauma and reducing pressure on the wound area. This dressing was previously shown to be effective for both wound healing and pressure injury prevention. <sup>17,18</sup>

This study was designed in response to the need to improve efficiency and quality of wound management in Spain. The main purpose was to study whether the use of this dressing can reduce the frequency of dressing changes and to analyze its impact on clinical practice in the context of routine clinical practice in Spanish primary care center (PCC) and nursing home (NH) patients.

## **METHODS**

An ambispective (retrospective and prospective) multicenter observational study was conducted in 30 Spanish PCCs and NHs. Facilities were located in four regions: Valencia (n = 12, 6 NHs and 6 PCCs), Extremadura (8 PCCs in Mérida), Galicia (2 PCCs in Orense), and Pais

Vasco (8 PCCs in Bilbao). The study was carried out between November 2017 and March 2019.

The HCPs at participating clinical sites were nurses. They recruited patients during routine wound care visits. The inclusion criteria were patients 18 years or older treated with occlusive dressings with an expected followup of at least 3 weeks and who presented with wounds indicated for use of the study dressing: shallow wounds requiring healing by second intention, chronic wounds, acute and exudating wounds, and partial- or full-thickness wounds such as pressure ulcers (PUs), leg ulcers (LUs), diabetic foot ulcers, surgical wounds, first- and seconddegree burns, skin graft donor sites, skin tears, and fungal ulcers. Patients with contraindications to the study dressing's use (eg, sensitivity to silicone gel adhesive dressings), those participating in clinical trials during the study or in the previous 6 months, or those presenting ulcers whose location and/or etiology required dressing changes for reasons not related to the intervention (eg, incontinence) were excluded.

All patients signed an informed consent form prior to the study in compliance with applicable regulatory requirements. The nurses had previously given their consent to participate. In each region, the study protocol was reviewed and approved by the local institutional review board. The study was conducted in accordance with the Good Clinical Practice guideline and the principles established in the Declaration of Helsinki. This research was funded by Smith + Nephew, who provided support for data analysis and manuscript authorship. The participating centers had previously used the study dressing in routine clinical practice and acquired them through their usual channels, except in Galicia, where their acquisition was pending at the beginning of the study and Smith + Nephew donated them free of charge.

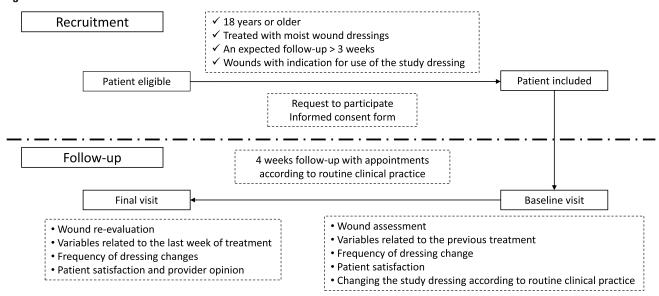
## Sample Size

In every participating region, a pilot study with approximately 30 participants was conducted. A sample of 30 participants is generally recommended to accurately estimate a parameter, and this sample size was used in similar studies conducted in Germany and the UK. 8,8,20

#### **Procedures**

The study period included two visits to capture wound data and collect study variables (Figure 1). Prior to the introduction of the study dressing, a baseline visit was conducted. During this visit, previous dressings were switched to the study dressing alongside other dressings as required. The decision to switch was based on the last week of treatment and was exclusively based on clinician judgment. The study dressing was applied by the nurses according to the manufacturer's instructions as either the primary or secondary dressing. All four sizes of this

Figure 1. STUDY FLOWCHART



dressing were used during the study based on wound size:  $10.3 \times 10.3$ ,  $12.9 \times 2.9$ ,  $15.4 \times 15.4$ , and  $21 \times 21$  cm.

After switching to the study dressing, patients were followed up for 4 weeks, and they attended appointments at their regular site for wound assessment, dressing change evaluation, and other treatment as usual. At week 4, a second and final visit was conducted, wounds were re-evaluated, and study variables regarding the last week of treatment were collected.

## **Data Collection and Outcome Measures**

Study variables were recorded by the nurses on an electronic case report form for each wound. If patients received wound care for multiple wounds, each one was reported and analyzed individually.

The primary endpoint was dressing change frequency, defined as mean number of completed dressing changes. This was collected from the medical record for previous dressings at baseline and for the study dressings at final visit. Dressing details included both primary and secondary dressings as necessary; that is, when the study dressing was used in combination with other dressing (as primary or secondary), all changes were accounted for.

Other variables collected included sociodemographic characteristics (type of center and age), wound characteristics (type and etiology, location, duration, depth, presence of local infection, and surrounding skin condition), and dressing-related variables (main reason for change and type, size, and number of dressings used). To diagnose local infection, HCPs considered signs and symptoms such as bleeding, hypergranulation, friable granulation, epithelial bridging and pocketing in granulation tissue, wound breakdown or enlargement,

delayed wound healing, new or increasing pain, increasing malodor, erythema, local temperature, swelling, and purulent discharge.<sup>21</sup>

Patient satisfaction was assessed using an ad hoc questionnaire that evaluated three items using a 5-point Likert-type scale (very poor, poor, adequate, good, very good): overall experience of wound care, control of wound exudate, and dressing comfort. At the final visit, an additional question was included determining if the patient would recommend the wound care received to friends and family (yes/no).

To assess nurse satisfaction with the study dressing (in direct comparison to previous dressings), an ad hoc questionnaire with a three-point scale (better, same, worse) was developed and administered at the final visit. First, HCPs assessed the evolution of the wound over the study period according to changes in wound size, exudate, smell, and pain. Second, HCPs assessed the following performance characteristics of dressings: ease of use, ability to adapt to wound size, exudate masking, ability to indicate the need for dressing change, ease of removal, overall dressing performance, and ability to involve the patient/caregiver. In addition, HCPs were asked whether they would recommend the use of the study dressings within their organization.

To describe the clinical impact on healing, wound area in centimeters squared was recorded at baseline and final visit, and changes in wound area were calculated in both exact area and percentage reduction over 4 weeks.

To describe the economic impact of changing dressings on expenses, mean weekly costs for previous dressings and the study dressing were calculated, as well as the weekly cost reduction.

### **Statistical Analysis**

A descriptive analysis of pooled data from the four regions was conducted. Absolute and relative frequencies were calculated to describe qualitative variables, whereas measures of centrality and dispersion (mean and SD) were calculated to describe the quantitative variables.

The frequency of dressing changes, wound area, and weekly cost per patient before and after switching to the study dressing were also compared. The comparison of quantitative variables was carried out using the t test and Wilcoxon test, depending on the results of the normality tests. P < .05 was considered statistically significant. To determine the internal validity of the findings, a post hoc power analysis was performed based on the primary endpoint showing a statistical power of 99%.

The analysis of weekly cost per patient was performed from the Spanish National Healthcare System perspective, thus excluding wounds cared for within NHs where supply and resource management are independent of the public healthcare system and dependent on social services. For calculating weekly cost per patient, unit dressing prices were multiplied by the number of primary and secondary dressings used and the number of changes per week retrospectively collected at baseline for the previous week and prospectively from baseline to final visit (4 weeks). Unit dressing prices were provided by each research team from the four participating regions, and an overall mean dressing price was calculated. Prices of the study dressings used were those established in the public tender for each region except Extremadura, where prices used correspond to the reimbursable financing prices established by the National Healthcare System for outpatients. In addition, the weekly cost per patient was calculated considering the mean cost of a nursing visit to treat wounds multiplied by frequency of changes. A mean cost of 27.79 € was estimated for each nursing visit according to the legally established cost for care in these regions.<sup>22</sup>

Investigators conducted a sensitivity analysis to evaluate the robustness of the cost analysis by the varying prices of the study dressing. Moreover, a subgroup analysis of change frequency and weekly cost per patient was performed for the most frequent type of wounds (PUs and LUs).<sup>23</sup>

For each study variable, data analysis was performed excluding wounds with missing data. Where wounds were lost to follow-up, the wound was excluded from the analysis. Statistical analysis was performed using SAS Software (version 9.4; SAS Institute, Cary, North Carolina).

## **RESULTS**

A total of 132 wounds from 95 eligible patients enrolled from PCCs (n = 80) and NHs (n = 15) were recorded; 1 patient with 4 wounds withdrew. Ultimately, 94 patients

Table 1. STUDY DRESSING PRICES USED IN COST ANALYSIS

Dressing Size, cm	Mean Price	Lowest Price	Highest Price
10.3 × 10.3	2.94€	1.50 €	4.55 €
12.9 × 12.9	2.85 €	1.80 €	3.95 €
15.4 × 15.4	3.74 €	3.00 €	4.55 €
21 × 21	6.77 €	4.30 €	9.24€

completed the study, and 128 wounds were included in the analysis (Galicia: 17 PCC patients/29 wounds; Pais Vasco: 23 PCC patients/30 wounds; Extremadura: 20 PCC patients/25 wounds; and Comunidad Valenciana: 19 PCC patients and 15 NH patients/29 and 15 wounds, respectively). The majority of patients (75.8%, n=71) were older than 70 years.

The overall mean, minimum, and maximum dressing prices are shown in Table 1. Table 2 shows the characteristics of wounds at baseline. The most frequent wounds were venous and mixed-etiology LUs (39.8%, n = 51) and PUs (31.3%, n = 40). Lower-extremity ulcers comprised 81.1% (n = 102) of wounds. In terms of duration, 37.5% (n = 48) of wounds had been present for less than 6 weeks, whereas 25.0% (n = 32) were older than 12 months.

Previous wound dressings used included foams, gelling fibers, protease-modulating dressings, contact layers, antimicrobials, and iodine dressings, among others, both alone and in combination. The study dressing was used as a secondary dressing in 64.8% of wounds (n = 83) mainly because of the need for debridement (n = 24) or suspected infection (n = 24). Other reasons included desloughing or deep wounds requiring packing. Dressings used in combination with the study dressing were mostly gelling fibers, protease-modulating dressings, and antimicrobials.

At baseline, the mean number of dressing changes was  $3.14 \pm 1.77$ ; at week 4, this was significantly reduced to  $1.66 \pm 0.87$  changes (P < .001), a reduction of 47.1%. Wound assessment was the main reason for dressing change at both data collection points (baseline, n = 44; final, n = 58); however, routine changes (baseline, n = 35; final, n = 17) and changes because the dressing was saturated (baseline, n = 24; final, n = 10) or stained (baseline, n = 14; final, n = 8) were reduced by 50%.

At the final visit, most wounds had reduced size (n = 85), pain (n = 76), smell (n = 70), and exudate level (n = 82) based on provider opinion. As shown in Figure 2, the study dressing was superior to previously used dressings for all the assessed performance characteristics according to the providers. Further, in 92.2% (n = 118) of cases, HCPs stated they would recommend the use of the study dressing within their healthcare organization. For the rest of the cases (n = 10), the HCP considered the previous dressings superior to the study dressing in

Table 2. BASELINE	<b>CHARACTERISTICS</b>	<b>OF</b>	<b>ANALYZED</b>
WOUNDS			

Characteristics of Wounds (n)	% (n)
Type of Ulcers (128)	
Pressure ulcer	31.3 (40)
Stage I	2.5 (1)
Stage II	15.0 (6)
Stage III	57.5 (23)
Stage IV	20.0 (8)
Unstageable	5.0 (2)
Leg ulcer	39.8 (51)
Trauma	6.3 (8)
Diabetic foot ulcer	4.7 (6)
Surgical wound	3.9 (5)
Burn	3.1 (4)
Others	10.9 (14)
Wound Location (126)	
Нір	11.1 (14)
Lower leg/shin	41.3 (52)
Malleolus/ankle	18.3 (23)
Rear foot/heel	15.1 (19)
Forefoot/toes	5.6 (7)
Others	10.2 (13)
Depth (128)	
Deep	52.3 (67)
Superficial	44.5 (57)
Unknown	3.1 (4)
Presence of Local Infection (127)	
Wounds with infection	29.1 (37)
Wounds without infection	68.5 (87)
Unknown	2.4 (3)
Wound Area (127)	
<2 cm <sup>2</sup>	22.0 (28)
2–10 cm <sup>2</sup>	55.1 (70)
>10 cm <sup>2</sup>	22.8 (29)

regard to characteristics such as the ability to adapt to the wound size (50%, n = 5), masking exudate (40%, n = 4), the ability to indicate the need for a change (50%, n = 5), and overall performance (40%; n = 4).

As shown in Figure 3, satisfaction with the overall experience of wound care, control of wound exudate, and dressing comfort all improved with the study dressing. Further, participants stated they would recommend their wound care in 90.2% of cases.

## **IMPACT ON CLINICAL OUTCOMES**

The baseline and 4-week wound areas were obtained for a total of 104 wounds. At baseline, mean wound area was  $9.90 \pm 19.62 \text{ cm}^2$ , which was significantly reduced to  $7.10 \pm 24.33 \text{ cm}^2$  after the intervention (P < .001), a reduction of 28.3%. Table 3 shows the percentage of area wound reduction over time for those wounds that decreased in size. At week 4, wound area had reduced in 68.3% (n = 71) of wounds analyzed (n = 104), with a reduction higher than 30% in most (85.9%, n = 61) cases.

## **Economic Impact**

The mean weekly cost for previous dressings versus the study dressing was  $27.70 \pm 94.60 \in$  and  $11.45 \pm 10.23 \in$ , respectively. The intervention resulted in a 58.6% reduction in weekly material cost (P < .001). This difference remained significant when adding in the mean cost of nursing time ( $108.82 \pm 123.70 \in$  vs  $55.78 \pm 33.67 \in$ , P < .01). Table 4 shows the percentage of cost reduction by the size of wound area at baseline.

Using the lowest and highest prices of the study dressing, sensitivity analysis showed that a reduction in weekly cost was achieved compared with previous dressings. Table 5 shows results for both scenarios. Significant differences in weekly costs were observed.

# **Subgroup Analysis**

For PUs, the mean number of dressing changes at baseline was  $3.43 \pm 1.74$ , which was significantly reduced at the final visit to  $1.90 \pm 0.78$  changes (P < .001). Mean weekly costs with previous dressings and during the intervention were  $47.99 \pm 163.76 \in$  and  $11.80 \pm 7.80 \in$ , respectively, another significant reduction (P < .001).

For LUs, the mean number of dressing changes at baseline was  $3.10 \pm 1.91$ , which was significantly reduced at the final visit to  $1.58 \pm 1.02$  changes (P < .001). Mean weekly costs were  $20.07 \pm 18.57 \in$  and  $13.00 \pm 13.44 \in$ , respectively, again showing a significant reduction (P < .001).

#### **DISCUSSION**

This study shows the impact of using a multilayer polyurethane foam dressing to improve the efficiency and quality of wound care among patients in Spanish PCCs and NHs.

The use of the study dressing, as both a primary and a secondary dressing, significantly reduced the frequency of dressing changes compared with other dressings used in routine clinical practice. These findings confirm the results of a previous study performed in the UK on patients with wounds treated with these dressings to determine usability, acceptability, and clinical performance in comparable settings. A similar reduction in change frequency was observed, albeit with a lower number of wounds analyzed. <sup>11</sup> Other previous studies have shown a similar reduction in dressing changes with this intervention. <sup>8</sup>

Evidence shows that the average frequency of dressing change is higher than 3 changes per week, <sup>2,24</sup> similar

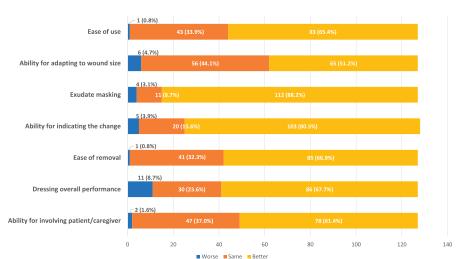


Figure 2. HEALTHCARE PROFESSIONAL SATISFACTION WITH THE STUDY DRESSING COMPARED WITH PREVIOUS DRESSING

to averages obtained with the previous dressings in this study. This would suggest that the dressing design (better absorption and change indicator system) reduced the number of unnecessary changes.

In terms of dressing costs and nursing time, the findings show that switching to the study dressing was associated with a reduced weekly cost per patient close to 50%. Further, high reductions in weekly costs per patient were achieved, mainly in wounds greater than 2 cm<sup>2</sup>. These results further highlight the importance of dressing change frequency in the overall costs of wound care.<sup>2</sup>

The percentage reduction in wound area has been established as a relevant indicator of healing.<sup>25,26</sup> The present results also demonstrate that with the use of the study dressing, wound area was significantly reduced

in a high percentage of wounds, with a majority demonstrating at least 30% reduction. Previous studies carried out in patients with venous ulcers have shown that this percentage reduction after 4 weeks is a good predictor of healing. <sup>25,27</sup>

Patient well-being is an important factor when considering adherence to therapy and is associated with healing. <sup>28</sup> The present study indicates that patients were largely satisfied with the intervention in terms of their experience of wound care, exudate control, and comfort. The absorbent core of the study dressing reduced malodor and leakage, and its design provided the comfortable wear that patients expect.

For any change to standard practice to succeed, the level of HCP satisfaction with the change needs to be

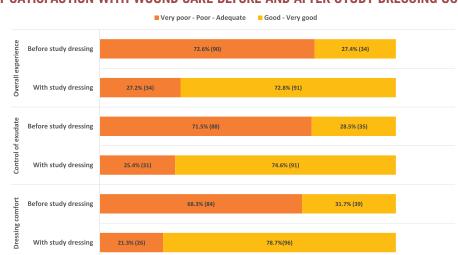


Figure 3. PATIENT SATISFACTION WITH WOUND CARE BEFORE AND AFTER STUDY DRESSING USE

Table 3. IMPACT OF THE STUDY DRESSING IN WOUND AREA REDUCTION

Period of Evolution	Wounds With Area Reduction				
		Mean Wound Area, cm <sup>2</sup>			
	n	Baseline	Week 4	Reduction, %	
<6 wk	30	9.10	1.45	84.1	
6 wk to 12 mo	29	8.38	4.62	44.9	
>12 mo	12	9.20	5.27	42.7	
Total	71	8.82	3.39	61.6	

high. This study shows a high degree of satisfaction with the dressings, with results in line with the findings of Stephen-Haynes et al,<sup>11</sup> who showed the intervention compared favorably with previous dressings in terms of ease of use, overall dressing performance, dressing wear time, and ability to stay in place.

#### Limitations

Although these findings are encouraging, this study has several limitations. First, because this was a real-world observational study based on routine clinical practice, patients were not randomized, and a control group was not used; several factors could have influenced the results. However, to overcome the lack of control, both standard care and the intervention were applied to the same wound at different times, and as such, each wound was considered its own control.

Second, because the baseline visit occurred at the time of dressing switch, data on wound characteristics and previous treatments and practices were collected retrospectively. Although retrospective studies have a risk of bias (largely because researchers do not have control over how the previously collected outcomes were measured), in this study, the same researcher assessed the previous and follow-up outcomes. In this way, the same measurement tools were used, and the variability in interpretation was likely reduced.

Third, the study sample size was calculated based on a standard pilot study to provide preliminary evidence

Table 4. IMPACT OF THE STUDY DRESSING IN WEEKLY COST PER PATIENT BY WOUND AREA AT BASELINE

	Wo	ounds With Area		
		Mean Weekly Co €		
<b>Baseline Wound Area</b>	n	Baseline	Week 4	Cost Reduction, %
<2 cm <sup>2</sup>	13	9.31	7.29	21.7
2-10 cm <sup>2</sup>	41	17.79	6.77	61.9
>10 cm <sup>2</sup>	15	93.26	17.84	80.9
Total	69	32.60	9.28	71.5

Table 5. RESULTS OF SENSITIVITY ANALYSIS IN BOTH SCENARIOS

Scenarios	Period	Mean	SD	n	P
Lowest price scenario	Before study dressing	27.8	94.6	125	<.001
	With study dressing	9.7	9.00	125	
Highest price scenario	Before study dressing	27.8	94.6	125	.0044
	With study dressing	13.4	11.6	125	

about the potential efficiency of the study dressing in real clinical practice in Spain. Although the ideal sample size was not maintained in all participating regions (which could limit the analysis by region), the authors included data from the regional pilot studies in this pooled analysis to provide rigor to the results. Thanks to the wide sample of wound types included in the analysis, statistically significant changes were found between previous dressings and the study dressing within specific wound types.

Fourth, because the primary objective of the study was to analyze if the newly introduced dressing met the need to improve efficiency and quality of care of wound management in the context of routine clinical practice, and because 4 weeks' follow-up was considered the appropriate period to achieve this objective, wound healing could not be assessed as a clinical outcome. Considering the vital importance of this outcome, further research should be conducted to assess whether the study dressing accelerates wound healing.

Finally, formal cost-effectiveness analysis is required to aid decisions about dressing selection. That said, current findings offer a first look at potential savings reached with these advanced dressings.

## **CONCLUSIONS**

The use of the study dressing in routine clinical practice could lead to a major improvement in both efficiency and quality of wound care. Because the frequency of dressing change is an important cost driver, the use of advanced technology such as this intervention could substantially reduce wound care-related costs. At the same time, the use of the study dressings enhanced HCP and patient satisfaction with care outcomes.

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