

**Actisorb post-marketing survey on 12,444  
difficult chronic wounds.**

**Clinical report**

**Draft 01**

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# 1 Introduction

Daily management of chronic wounds is in most cases a difficult challenge.

In spite of recent advances in the basic mechanisms of wound healing, knowledge of the factors involved in the development and treatment of chronic wounds remains limited. Future progress in the treatment of chronic wounds will require greater understanding of their pathogenesis and failure to heal [1-3].

Among involved factors, bacterial colonization and infection may play an important role to explain healing delay [4,5]. This is well documented when a concomitant diabetes mellitus is present. However, the definition of an infected chronic wound is difficult and not precisely defined [6-8]. For instances, stage II, III, and IV pressure ulcers are invariably colonized with bacteria. In most cases, adequate cleansing and debridement prevent bacterial colonization from proceeding to the point of clinical infection. Nevertheless some studies have suggested that approximately 25 percent of nonhealing pressure ulcers have underlying osteomyelitis [9,10].

No controlled studies have documented that repeated topical application of antiseptics to the surface of chronic wounds regarded at high risk to develop infection significantly decreases the level of bacteria within the wound tissue. Numerous studies, however, have documented the toxic effects of exposing wound-healing cells to antiseptics [11,12].

Therefore, when caregivers are facing this problem, the possibility to use a dressing such as Actisorb may be considered as an interesting alternative.

Indeed, Actisorb Plus comprises of a charcoal cloth consisting of 95-98% carbon, produced by carbonizing and activating a knitted viscose rayon fabric. The rayon fabric is enclosed in a sleeve of spun-bonded non-woven nylon, sealed along all four edges, to facilitate handling of the dressing and to reduce particle and fibre loss.

When used as a dressing, activated charcoal has the ability to adsorb toxins and wound degradation products as well as volatile fatty acids responsible for the production of wound odor.

It has been shown in laboratory studies that certain microorganisms appear to be attracted to the surface of the charcoal cloth and thus removed from aqueous suspension. Thus in vivo, the use of Actisorb Plus may help to reduce the bioburden of the wound and thus improve the healing environment. This effect is enhanced by the inclusion in the dressing of silver residues that are chemically and physically bound within the structure of the carbon fibres. These

impart antimicrobial properties to the fabric and further help to prevent the growth or proliferation of bacteria bound to the dressing surface.

These properties have been documented in various clinical trials [13-15] but the handling of this device in “natural” conditions of medical practices was not yet described.

This was the main objective of a series of post-marketing studies conducted in Germany between 1996 and 2000 which results are thereafter presented.

## **2 Study protocols and data management**

Between 1996 and 2000 five observational studies were conducted in Germany with Actisorb. All these studies followed a similar protocol including either a 6 or a 12-week follow-up period and their results were pooled in a single analysis.

### **2.1 Study protocols**

Participating Investigators were general practitioners, dermatologists or surgeons.

In and outpatients either male or female with no age limitation were included in these surveys if they met the following criteria:

- Presence of a chronic wound (i.e. wound present since 4 weeks or more) of whatever origin.
- Decision of the treating physician to initiate Actisorb on a routine basis.

It was asked to investigators to notify at least 3 successively seen patients.

A standardized Case Report form was used to collect data at baseline and at last visit (at 6 or 12 weeks or earlier in case of healing or of dressing discontinuation).

At baseline the following parameters were recorded: patients' age and sex, concomitant diseases, wound history, nature, grade, localization, size (length and width) and history of the lesion. Main wound characteristics (presence of exsudation, odor, necrotic tissue, fibrinous deposits, granulation tissue, epithelialization tissue) were scored according to a 4-item scale (none, small, extensive, entire area). Wound depth was categorized as superficial, deep, wound pouch, deep/pouch. Presence or not of local clinical signs of infection were reported. Previous used dressing was recorded as well as previous treatments (local or systemic) of infection if any and the main reason to select Actisorb in these patients.

At last visit, the same parameters were recorded. In addition, the mean number of Actisorb changes per week was notified. The global investigators' opinion concerning Actisorb

efficacy or interest was asked for each treated wound with regards to the following criteria: treatment of infection, healing capabilities, tolerability, dressing handling and patients' compliance. The same opinion was also asked with regards to previous local treatment. Finally, decision of investigators to include Actisorb in his/her usual therapeutic scheme was recorded.

## **2.2 Data management**

Metronomia did data entry and statistical analysis by means of the SAS system (version 6.12). All parameters were analyzed descriptively for the relevant subgroups and presented as following:

- Number of data
- Arithmetic mean, standard deviation
- Median, minimum, maximum
- 95% confidence limits.

The wound radius (cm) was estimated as the square root of  $[(width \times length)/\pi]$ .

Nominally and ordinally scaled parameters were presented with their absolute and relative (in percent) frequencies.

Study flow-charts and pooled data are presented thereafter.

	ACTISORB						
	Metronmia Project ID					pooled/analysed	
	JJ02	JJ05	JJ08	JJ10	JJ13	yes	partly
Patient's sex	✓	✓	✓	✓	✓	✓	
Patient's age	✓	✓	✓	✓	✓	✓	
Type of wound	✓	✓	✓	✓	✓	✓	
Localisation of wound	✓	✓	✓	✓	✓	✓	
Age (weeks) , size (radius in cm) and depth of wound (superficial/deep/wound pouch/deep+pouch) at baseline and after 6/12 weeks*	✓	✓	✓	✓	✓	✓	
Concomitant diseases	✓		✓	✓	✓		✓
Wound status after 6/12 weeks* (healed/improved/unchanged/aggravated)	✓	✓	✓	✓	✓	✓	
Wound characteristics at baseline and after 6/12 weeks*							
danger of infection (yes/no)	✓	✓	✓	✓	✓	✓	
signs of infection (yes/no)	✓	✓	✓	✓	✓	✓	
exudation (none/little/medium/strong)	✓	✓	✓	✓	✓	✓	
wound odour (none/little/medium/strong)	✓	✓	✓	✓	✓	✓	
amount of necrotic tissue (none/small/extensive/entire area)	✓	✓	✓	✓	✓	✓	
amount of fibrinous adhesion (none/small/extensive/entire area)	✓	✓	✓	✓	✓	✓	
amount of granulation tissue (none/small/extensive/entire area)	✓	✓	✓	✓	✓	✓	
amount of epithelialisation (none/small/extensive/entire area)	✓	✓	✓	✓	✓	✓	
Previous Treatments							
ointment/compress/gauze (yes/no)	✓	✓	✓	✓	✓	✓	
hydrokolloid (yes/no)	✓	✓	✓	✓	✓	✓	
Frequency of bandage changes during previous treatment (number per week)					✓		✓
Frequency of bandage changes during ACTISORB treatment (number per week)		✓	✓	✓	✓		✓
Reasons for switching to ACTISORB							
side effects	✓	✓	✓	✓	✓	✓	
costs	✓	✓	✓	✓	✓	✓	
lack of efficacy	✓	✓	✓	✓	✓	✓	
patient's wish	✓	✓	✓	✓	✓	✓	
compliance	✓	✓	✓	✓	✓	✓	
antibiotic resistance			✓	✓	✓		✓
Concomitant medication for infections (local antibiotic/systemic antibiotic/ointments)	✓	✓	✓	✓	✓	✓	
Cosmetic result of treatment	✓	✓	✓	✓	✓	✓	
Size of applied bandages	✓						
Side effects (yes/no; kind of side effects)	✓	✓	✓	✓	✓	✓	
Premature termination of therapy (yes/no; reason)	✓	✓	✓	✓	✓	✓	
Assessment of treatment by the doctor after 6/12 weeks*							
efficacy (with regards to infections)	✓		✓	✓			✓
efficacy (with regards to healing)	✓	✓	✓	✓			✓
tolerability	✓	✓	✓	✓			✓
handling	✓	✓	✓	✓			✓
compliance	✓		✓	✓			✓
economic efficiency	✓						
Assessment of treatment by the doctor in comparison to previous treatment after 6/12 weeks*							
efficacy (with regards to infections)	✓		✓	✓	✓		✓
efficacy (with regards to healing)	✓				✓		✓
tolerability	✓		✓	✓	✓		✓
handling	✓		✓	✓	✓		✓
compliance	✓		✓	✓			✓
Missing sizes		✓	✓	✓	✓		✓
Reasons for including TIELLE/ACTISORB into the standard therapeutic scheme	✓		✓	✓	✓		✓
Outstanding characteristics of TIELLE/ACTISORB					✓		✓
Suggestions for optimisation of TIELLE/ACTISORB					✓		✓
General comments	✓	✓	✓	✓			✓

\* In PMS study JJ13 all patients were documented over a period of 12 weeks compared to 6 weeks in the other ACTISORB PMS studies). Therefore, the analysis for the marked endpoints will be separated according to the documentation period.

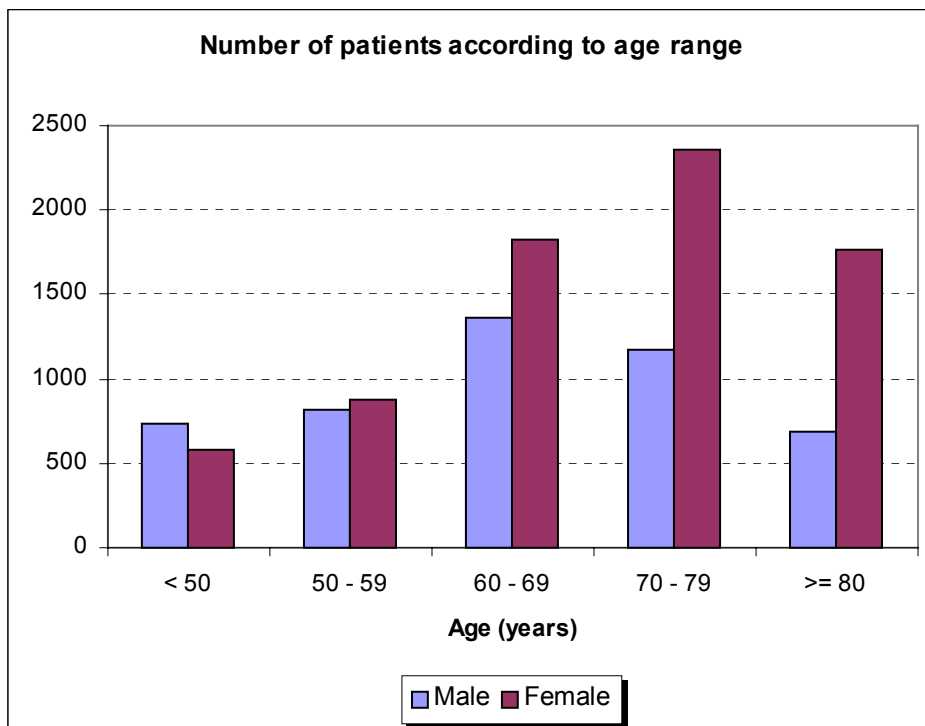
### 3 Description of the population at baseline

Between 1996 and 2000 a total of 12 444 wounds were treated in \*\*\*\* patients with Actisorb over periods ranging from 6 to 12 weeks. \*\*\*\* investigators participate to this surveys.

Study code	Number of wounds
JJ02	3,703
JJ05	788
JJ08	5,265
JJ10	935
JJ13	1,753
<b>Total</b>	<b>12,444</b>

#### 3.1 Population

The mean age of the included patients was 67.5 ± (SD) 14.4 years and 60.8% of the population was female. On average women were older than men.

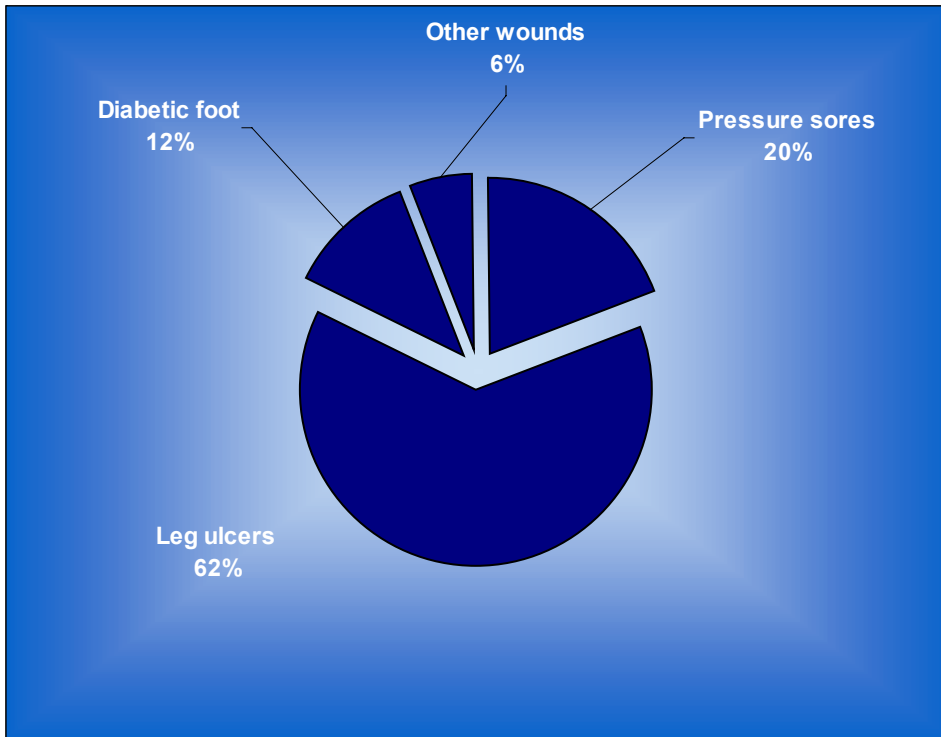


In 74% of the total population a concomitant disease was noticed. 42.0% of the patients were suffering from a circulatory disorder and 32.4% were diabetics. Malnutrition was reported in 8.0% of the patients, a malignancy in 4.5%.

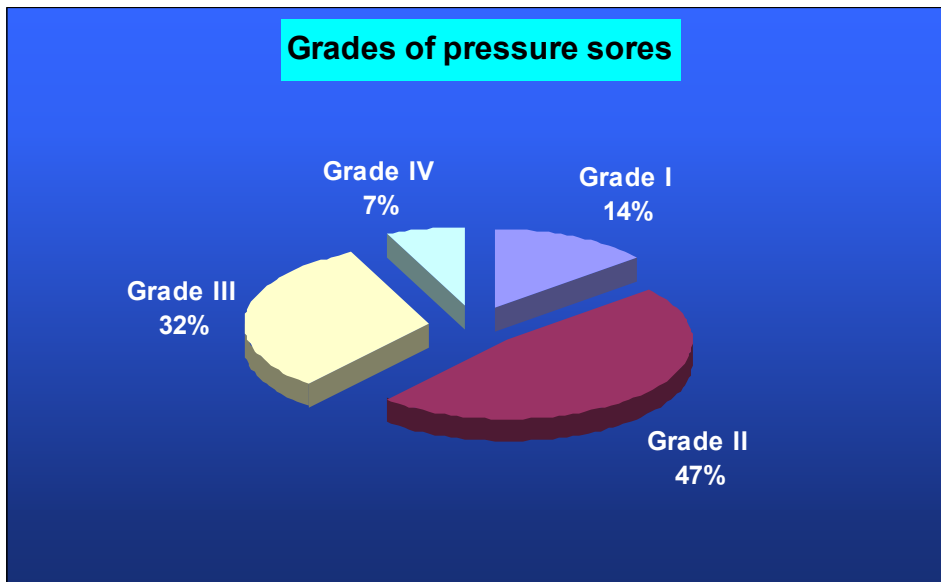
### 3.2 Wounds

#### 3.2.1 Type of wounds

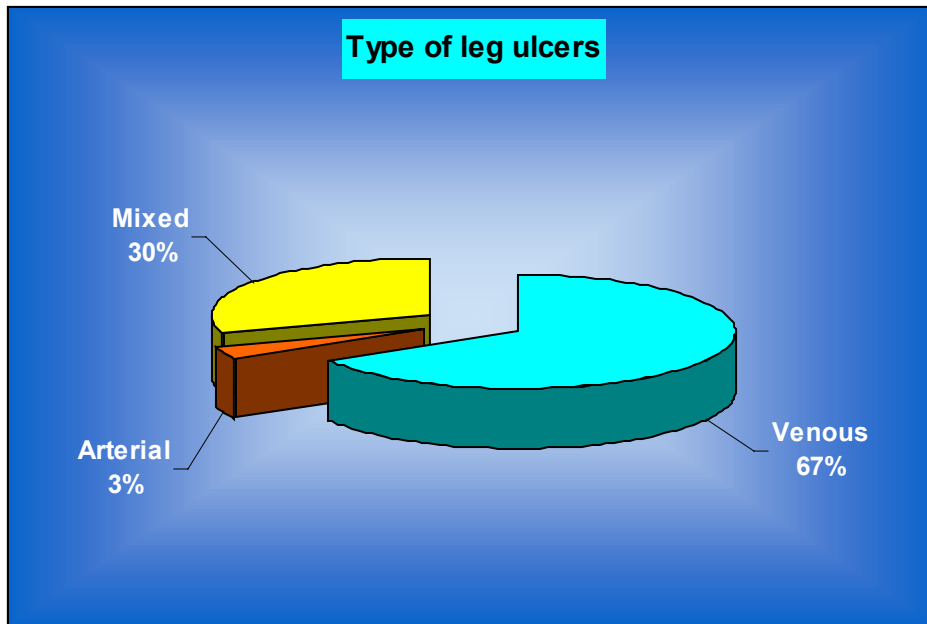
7798 wounds (62%) were leg ulcers, 2435 (20%) pressure sores, 1493 (12%) diabetic foot lesions and 718 (6%) were various wounds (mainly traumatic or post-surgical wounds).



47% of pressure sores were classified as grade II and 39% as grade III to IV.



Leg ulcers were predominantly of a venous origin (67% of cases).



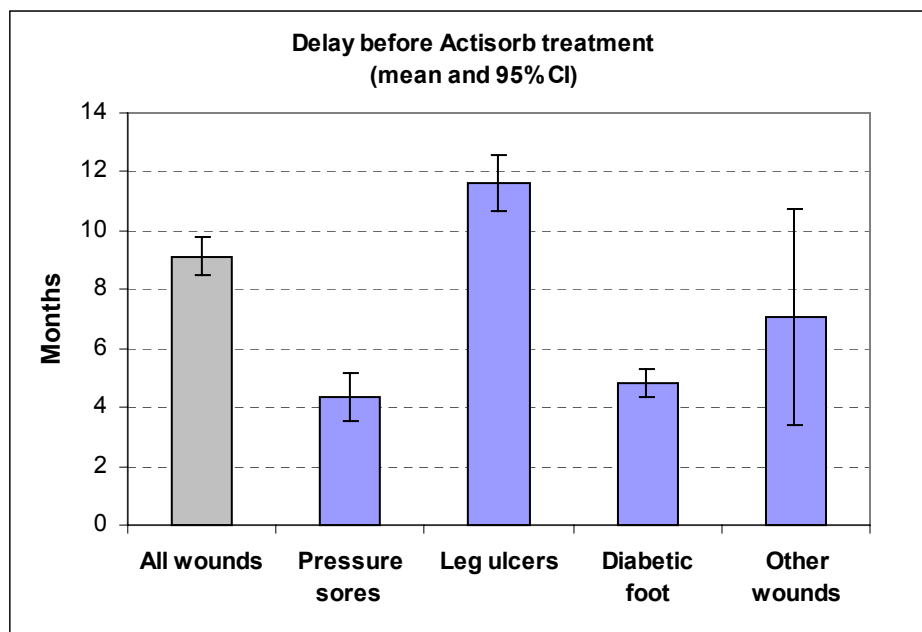
The principal cause of diabetic foot lesions was neuropathic in 58% of cases and was an arterial peripheral disease in the remaining patients.

When documented 41% of the other wounds were post-traumatic and 25% post-surgical.

### 3.2.2 Wound history

Before initiating treatment with Actisorb, wounds were present for  $9 \pm 38$  months on average.

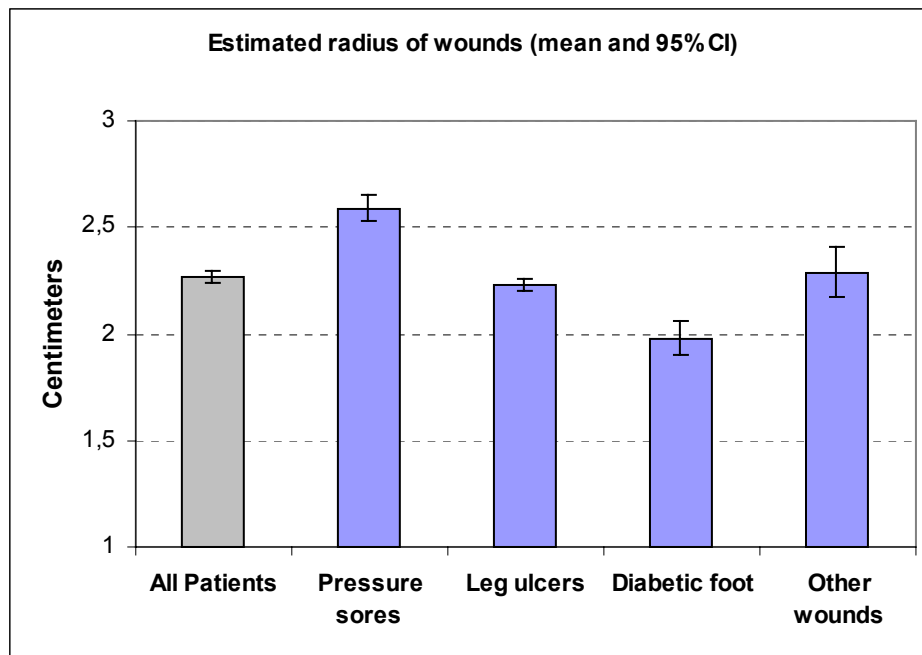
This delay was ranging from  $4 \pm 20$  months in pressure up to  $12 \pm 43$  months in leg ulcers.



### 3.2.3 Wounds characteristics

From 56% to 66% of wounds were deep. Moderate to strong exsudation was present in more than 60% of cases and a moderate to strong odor was noticed in up to 57% of the lesions mainly in pressure sores.

The mean estimated radius of wounds was  $2.3 \pm 1.7$  cm with 10% of the lesions presenting at baseline a radius greater than 4 cm.



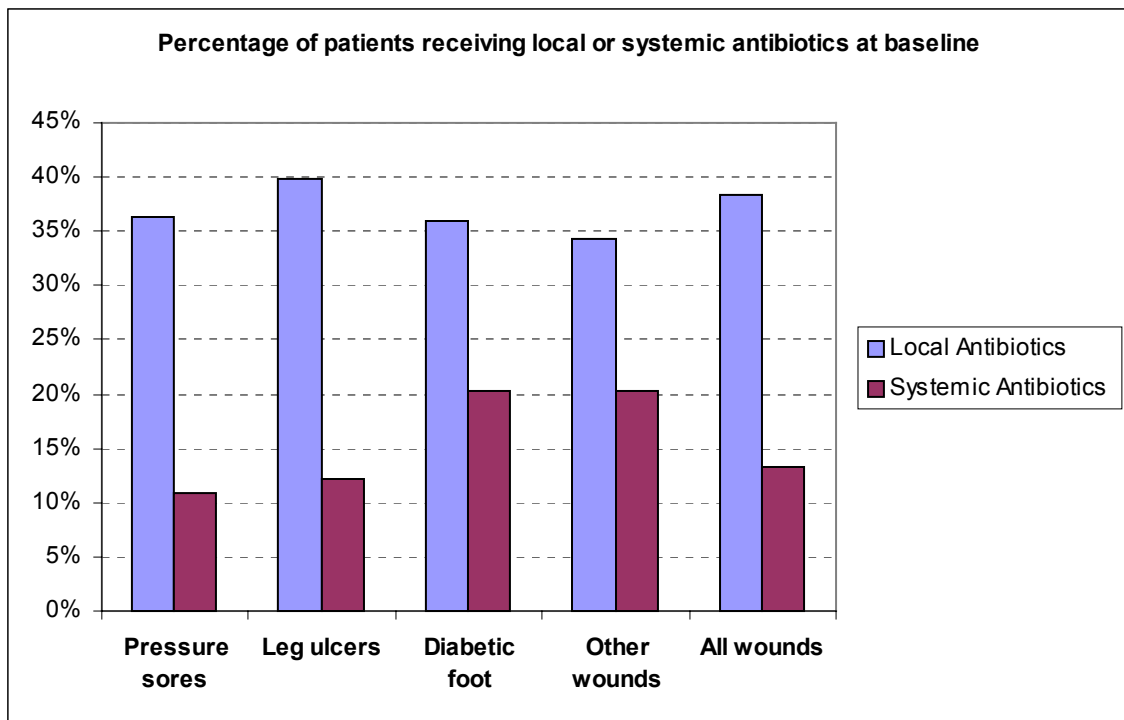
Extensive necrotic tissue and fibrinous deposit were present in 33% to up to 49% of wounds and no or few granulation tissue was reported in almost all patients.

**Table 1. Baseline characteristics of wounds (% of wounds)**

	<i>Pressure Sore</i>	<i>Leg ulcers</i>	<i>Diabetic foot</i>	<i>Other wounds</i>
<i>Deep or deep/pouch</i>	66.4%	56.1%	64.4%	61.2%
<i>Signs of infection</i>	64.4%	62.7%	69.6%	74.4%
<i>Moderate to strong exudation</i>	64.2%	65.5%	63.7%	66.9%
<i>Moderate to strong odor</i>	57.4%	47.5%	48.1%	42.0%
<i>Extensive necrotic tissue</i>	48.8%	33.1%	44.8%	37.7%
<i>Extensive fibrinous deposit</i>	38.4%	41.9%	35.1%	40.3%
<i>No or few granulation tissue</i>	94.5%	94.6%	94.3%	93.4%

Signs of infection were present in more than 60% of these wounds, mainly in diabetic foot lesions (64%) and in the post-traumatic or –surgical wounds (74%).

Local and/or systemic antibiotics were used in respectively 38% and 13% of wounds.



### 3.2.4 Previous dressing

Most of the wounds were previously treated with gauzes and ointments and an hydrocolloid dressing was used in 8% to 15% of the cases.

**Table 2. Previous dressing (% of wounds)**

	<i>Ointment, Gauze</i>	<i>Hydrocolloid</i>	<i>Other</i>
<b><i>Pressure Sore</i></b>	76.9%	13.7%	6.1%
<b><i>Leg ulcers</i></b>	74.3%	15.3%	6.6%
<b><i>Diabetic foot</i></b>	78.1%	11.1%	6.0%
<b><i>Other wounds</i></b>	80.3%	7.6%	6.5%
<b><i>All wounds</i></b>	75.6%	14.0%	6.4%

Whatever the previous local treatment, a lack of efficacy was noted as one of the reasons to change to Actisorb in 83% of the cases. The next most frequently reported reasons were patients' wishes to change or compliance to previous dressing noticed in 16% and 14% of the cases respectively.

## 4 Efficacy results

### 4.1 Patients' follow-up

10 691 patients (86% of the total population) were included in 6-week follow-up studies (mean follow-up:  $44 \pm 21$  days) and 1 753 in 12-week trials (mean follow-up:  $57 \pm 29$  days).

**Table 3. Percentage of patients according to wound types and follow-up duration**

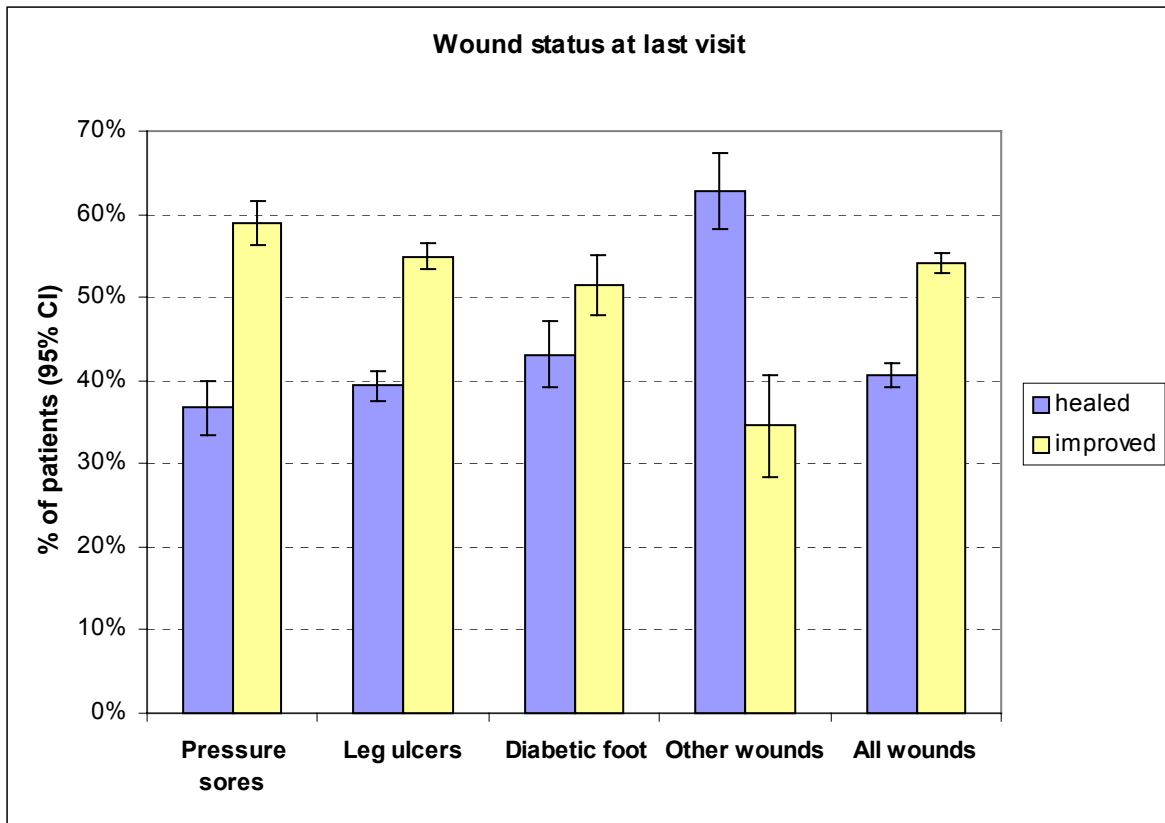
	<b>6 weeks</b>	<b>12 weeks</b>
<b>Pressure sores</b>	85.5%	14.5%
<b>Leg ulcers</b>	86.4%	13.6%
<b>Diabetic foot</b>	87.1%	12.9%
<b>Other wounds</b>	80.2%	19.8%
<b>Total population</b>	85.9%	14.1%

### 4.2 Healing rate

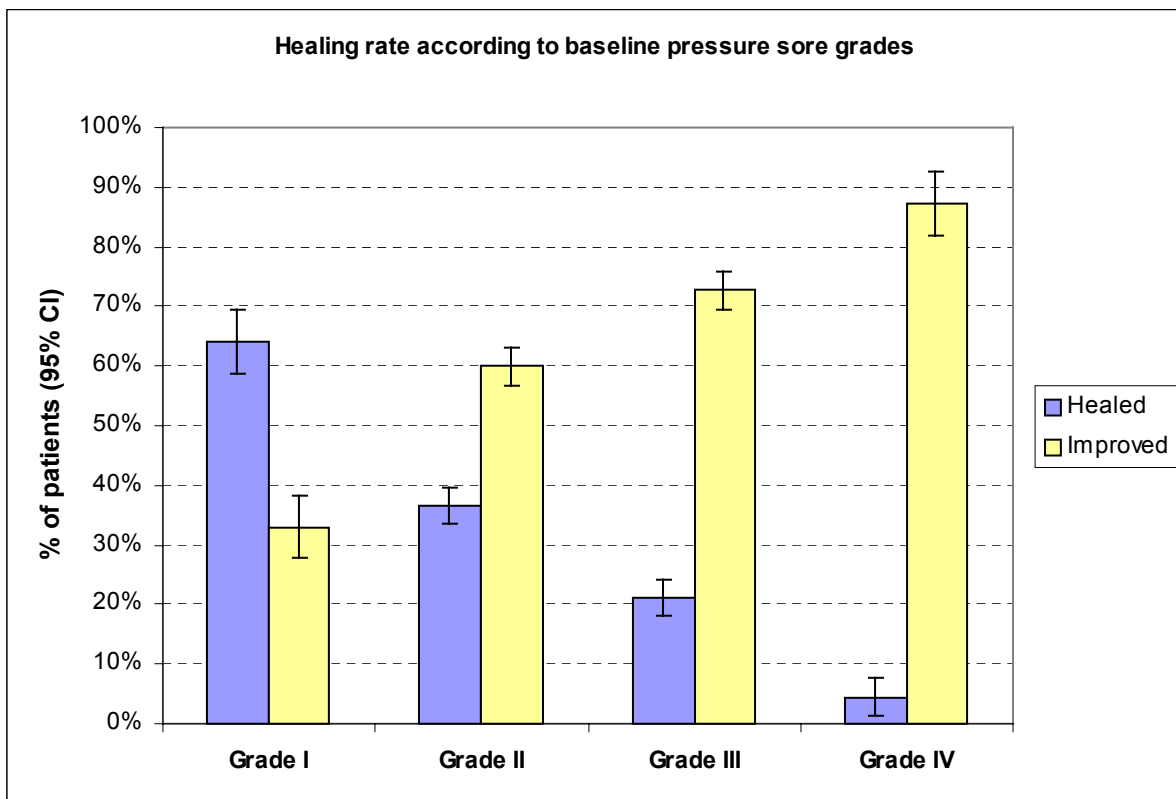
When considering the wound status at last visit whatever the actual planned follow-up duration, 41% of all wounds healed. The healing rate was the greatest in the post-traumatic or post-surgical wounds (63%) and was almost similar for the other types of wounds (from 37% to 41%). On the opposite only 0.7% to 1.7% of wounds worsened.

**Table 4. Percentage of healed wounds at last visit**

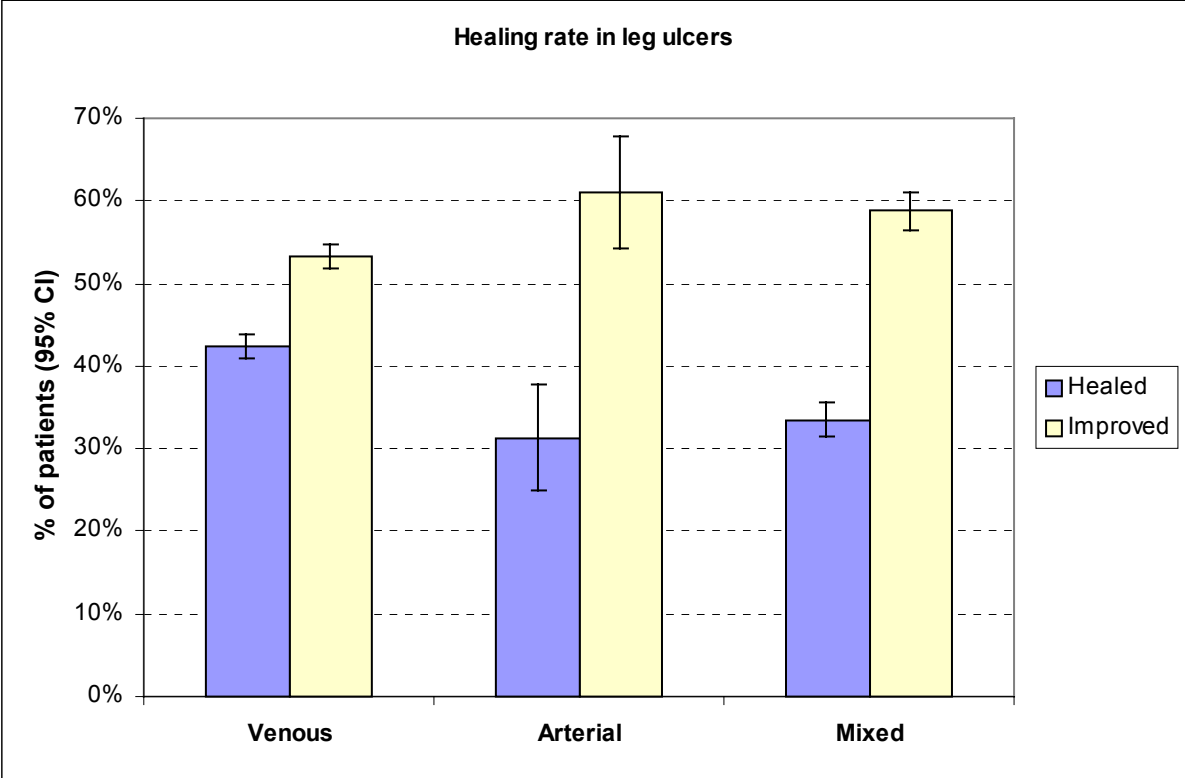
	<b>Healed</b>	<b>Improved</b>	<b>Unchanged</b>	<b>Aggravated</b>
<b>Pressure sores</b>	36.7%	58.9%	3.1%	1.2%
<b>Leg ulcers</b>	39.3%	55.0%	4.4%	1.3%
<b>Diabetic foot</b>	43.2%	51.5%	3.6%	1.7%
<b>Other wounds</b>	62.8%	34.5%	1.9%	0.7%
<b>All wounds</b>	40.7%	54.1%	3.9%	1.3%



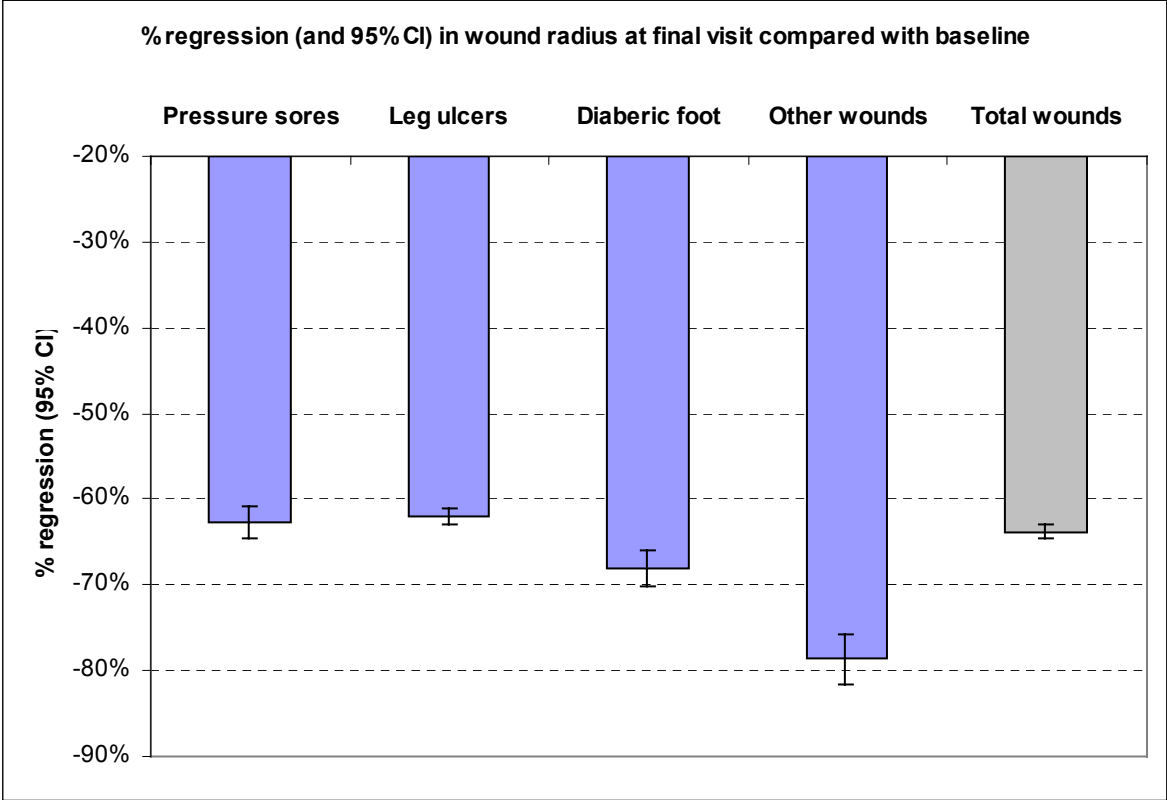
In pressure sores, the healing rate decreased from 64% to 5% according to the severity of wound grade at baseline. However, almost all grade IV pressure sores improved at last visit.



In leg ulcers, ulcer of venous origin were the most prone to heal within 6 to 12-week (42% healed) while around 30% of the ulcers of arterial or mixed origin healed in the mean time.



In parallel to healing, wound radius dropped on average by 64% at last visit as compared to baseline.



### 4.3 Wounds characteristics at last visit

When not healed, almost all wounds dramatically improved with Actisorb. In less than 9% of the wounds extensive necrotic tissue, fibrinous deposits or moderate to strong exsudation were still present.

**Table 5. Wound characteristics of non-healed lesions at last visit**

	<i>Pressure sores</i>	<i>Leg ulcers</i>	<i>Diabetic foot</i>	<i>Other wounds</i>	<i>Total wounds</i>
<i>Deep/pouch</i>	16.4%	10.4%	13.6%	7.8%	11.8%
<i>Moderate to strong exsudation</i>	7.8%	9.4%	7.1%	5.2%	8.6%
<i>Moderate to strong odor</i>	4.4%	3.4%	4.5%	1.3%	3.6%
<i>Extensive necrotic tissue</i>	3.1%	2.3%	4.9%	2.4%	2.8%
<i>Extensive fibrinous deposit</i>	7.2%	5.8%	7.8%	3.9%	6.2%

### 4.4 Signs of infection at last visit

While signs of infections were reported in 65% of the wounds at baseline, this was still mentioned in no more than 7% of wounds at last visit.

**Table 6. Presence of signs of infection at baseline and at last visit**

	<i>Baseline</i>	<i>Final visit</i>
<i>Pressure sore</i>	64.4%	6.9%
<i>Leg ulcers</i>	62.7%	7.6%
<i>Diabetic foot</i>	69.6%	7.8%
<i>Other wounds</i>	74.4%	5.3%
<i>Total wounds</i>	64.5%	7.4%

One of the consequences of this favorable evolution is the dramatic decrease in the concomitant use of local treatments aiming at treating infection. Indeed, only 18% of wounds at baseline did not required the use of local concomitant treatment and this percentage increased up to 80% at last visit with Actisorb.

**Table 7. % of wounds not requiring concomitant use of local treatments at baseline and at last visit**

	<i>Baseline</i>	<i>Final visit</i>
<i>Pressure sore</i>	17.8%	80.4%
<i>Leg ulcers</i>	17.7%	81.9%
<i>Diabetic foot</i>	17.1%	72.6%
<i>Other wounds</i>	18.5%	79.2%
<i>Total wounds</i>	17.7%	80.4%

## 4.5 Cosmetic results

Cosmetic results of healed wounds were graded by investigators as excellent in 58% to 71% of wounds.

**Table 8. Excellent cosmetic results in the 6-week follow-up studies**

	<b>% of wounds</b>
<i>Pressure Sore</i>	57,7%
<i>Leg ulcers</i>	58,9%
<i>Diabetic foot</i>	64,4%
<i>Other wounds</i>	71,2%

## 4.6 Number of dressing changes during study follow-up

Numbers of dressing changes were available for 8508 wounds.

On average Actisorb dressings were changed  $3.8 \pm 2.2$  times per week (median : 3 changes per week). There was no relevant difference of the number of weekly changes according to the nature of wounds.

# 5 Tolerability results

## 5.1 Drop-outs

Excluding healing or improvement, Actisorb dressing was stopped in 635 patients before the planned end of the study (global drop-out rate: 5.3%).

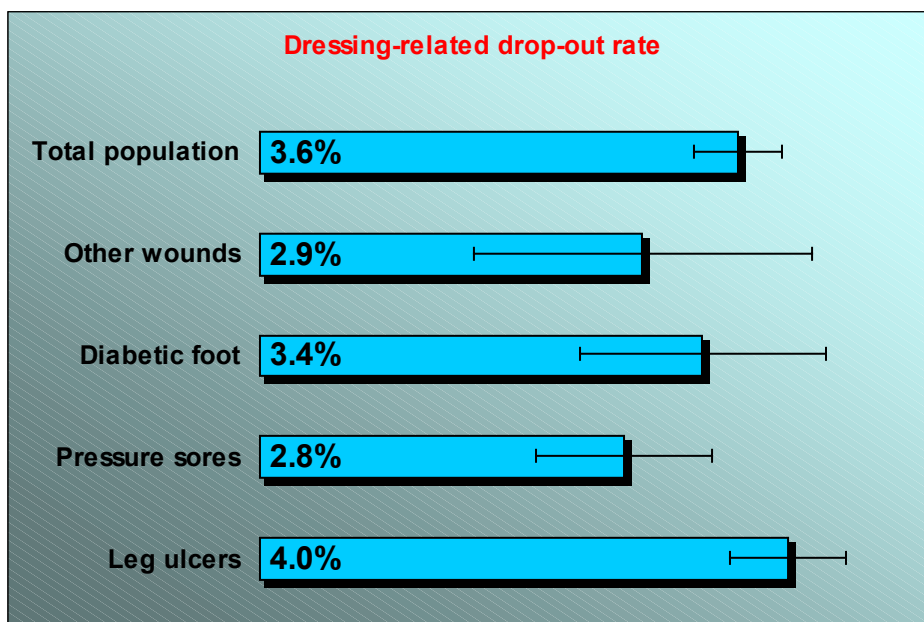
In 200 cases, reason to stop Actisorb was not dressing-related. 65 patients died during the course of the trial, 78 were not evaluated at last visit due to an intercurrent problem or to an hospitalization and 57 for another reason (patients moved out, etc.).

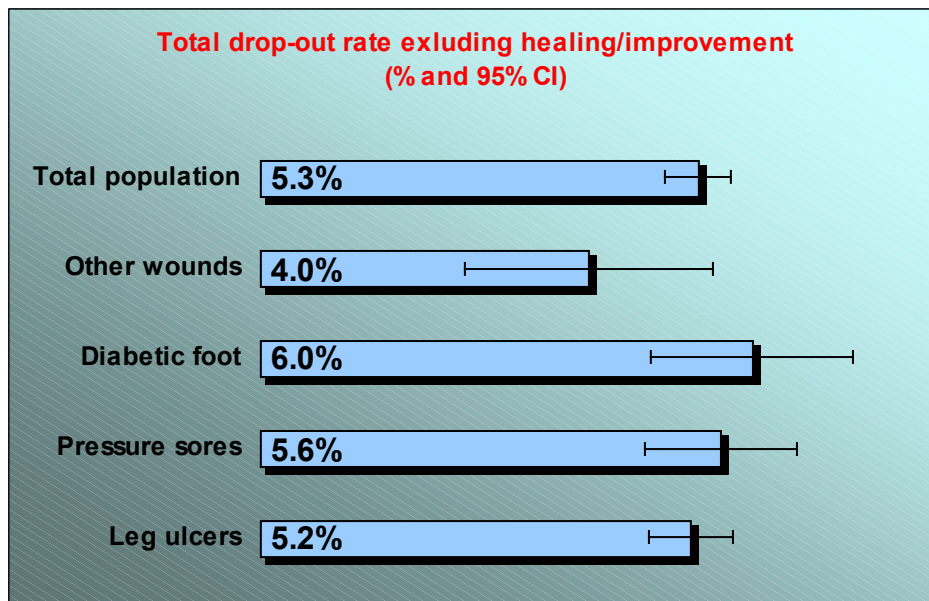
For 435 wounds (3.6%), the main reason to stop dressing might be related to the used dressing. The main cause was an insufficient efficacy or a worsening of the wound (130 cases). Local intolerance, irritation or local pain or itching were reported in 108 patients, mainly in leg ulcers.

Overall, the dressing-related dropout rate was 3.6% and ranged from 2.8% to 4.0% according to wound types.

**Table 9. Reasons to dropout**

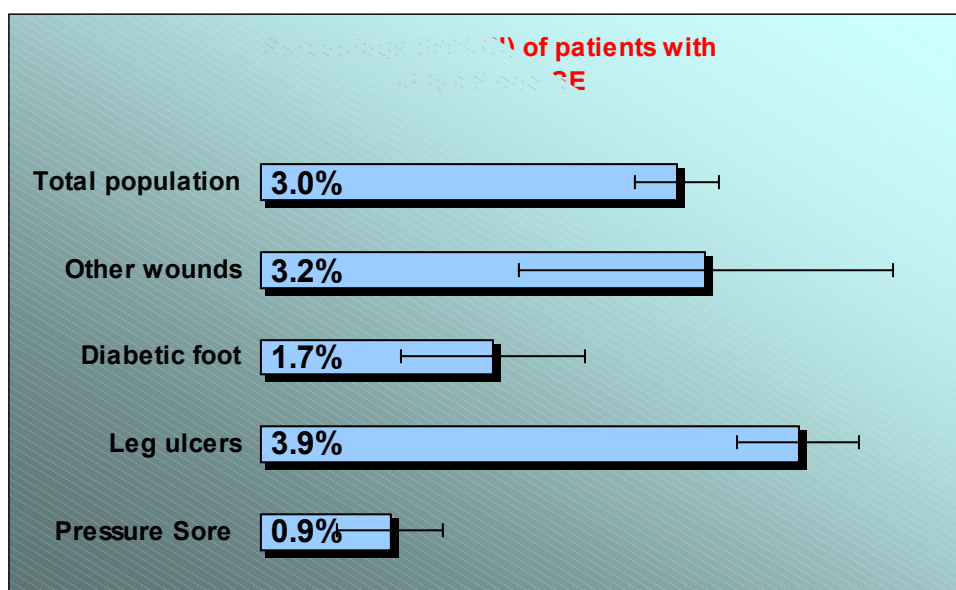
Reason to drop-out	Leg ulcers	Pressure sores	Diabetic foot	Other wounds	Total population
<b>• Not-dressing related reasons</b>					
<i>Intercurrent problem not dressing related / Hospitalizations</i>	42	14	19	3	<b>78</b>
<i>Death</i>	9	48	5	3	<b>65</b>
<i>Other reasons not dressing related</i>	39	4	13	1	<b>57</b>
<b>Total</b>	<b>90</b>	<b>66</b>	<b>37</b>	<b>7</b>	<b>200</b>
<b>• Possible dressing-related reasons</b>					
<i>Insufficient efficacy / Worsening</i>	97	13	17	3	<b>130</b>
<i>Burning / Pain/ Itching</i>	42	2	6	4	<b>54</b>
<i>Local Intolerance / irritation</i>	52	0	1	1	<b>54</b>
<i>Costs</i>	3	32	0	0	<b>35</b>
<i>Not specified</i>	22	6	2	3	<b>33</b>
<i>Change of therapy</i>	22	1	4	1	<b>28</b>
<i>Non-compliance</i>	18	1	4	3	<b>26</b>
<i>Change of physician / hospital</i>	12	5	5	1	<b>23</b>
<i>Patient's wish</i>	9	1	2	0	<b>12</b>
<i>Infection</i>	7	1	1	1	<b>10</b>
<i>Maceration / Excessive exsudation</i>	4	3	0	1	<b>8</b>
<i>Lost to follow-up</i>	6	0	1	0	<b>7</b>
<i>Allergy</i>	3	0	2	0	<b>5</b>
<i>Adhesion to wound</i>	4	0	0	0	<b>4</b>
<i>Dressing size not adequate</i>	0	0	2	0	<b>2</b>
<i>Skin graft</i>	1	0	0	1	<b>2</b>
<i>Contact eczema</i>	1	0	0	0	<b>1</b>
<i>Over granulation</i>	0	0	1	0	<b>1</b>
<b>Total</b>	<b>303</b>	<b>65</b>	<b>48</b>	<b>19</b>	<b>435</b>
<b>Total drop-out rate</b>	<b>5.2%</b>	<b>5.6%</b>	<b>6.0%</b>	<b>4.0%</b>	<b>5.3%</b>
<b>Dressing related drop-out rate</b>	<b>4.0%</b>	<b>2.8%</b>	<b>3.4%</b>	<b>2.9%</b>	<b>3.6%</b>





## 5.2 Side-effects

At least one side-effect (dressing- or not dressing-related) was reported in 361 patients (3.0% of total population). According to wound type, prevalence of side-effects ranged from 0.9% in pressure sores up to 3.9% in leg ulcers.



In 32 cases, the nature of the side-effect was not mentioned. When specified, no side-effect was reported in more than 1% of patients.

The most frequently reported side-effects were “pain” noticed in 103 patients (0.86%), mainly in leg ulcers, “burning” in 71 subjects (0.59%), “intolerance” (with no precision) in 30 patients (0.25%) and “redness” in 15 (0.13%).

The prevalence of other side-effects was inferior to 0.1%.

**Table 10. Prevalence of side-effects**

	<i>Leg ulcers</i>		<i>Diabetic foot</i>		<i>Other wounds</i>		<i>Pressure Sore</i>		<i>Total population</i>	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
<i>Pain</i>	91	1.21%	6	0.42%	4	0.62%	2	0.09%	<b>103</b>	<b>0.86%</b>
<i>Burning</i>	55	0.73%	5	0.35%	6	0.92%	5	0.21%	<b>71</b>	<b>0.59%</b>
<i>Intolerance</i>	27	0.36%	2	0.14%	.	-	1	0.04%	<b>30</b>	<b>0.25%</b>
<i>Redness</i>	14	0.19%	.	-	1	0.15%	.	-	<b>15</b>	<b>0.13%</b>
<i>Adhesion with wound</i>	9	0.12%	1	0.07%	.	-	.	-	<b>10</b>	<b>0.08%</b>
<i>Exudation</i>	8	0.11%	1	0.07%	1	0.15%	.	-	<b>10</b>	<b>0.08%</b>
<i>Infection</i>	7	0.09%	2	0.14%	.	-	1	0.04%	<b>10</b>	<b>0.08%</b>
<i>Allergy</i>	6	0.08%	.	-	.	-	1	0.04%	<b>7</b>	<b>0.06%</b>
<i>Itching</i>	6	0.08%	1	0.07%	1	0.15%	3	0.13%	<b>11</b>	<b>0.09%</b>
<i>Drying of wound</i>	5	0.07%	.	-	1	0.15%	.	-	<b>6</b>	<b>0.05%</b>
<i>Adhesion</i>	3	0.04%	1	0.07%	.	-	.	-	<b>4</b>	<b>0.03%</b>
<i>Irritation</i>	3	0.04%	.	-	1	0.15%	.	-	<b>4</b>	<b>0.03%</b>
<i>Bleeding</i>	2	0.03%	1	0.07%	1	0.15%	.	-	<b>4</b>	<b>0.03%</b>
<i>Worsening</i>	2	0.03%	.	-	.	-	1	0.04%	<b>3</b>	<b>0.03%</b>
<i>Thinning of skin</i>	.	-	.	-	.	-	1	0.04%	<b>1</b>	<b>0.01%</b>
<i>Edema</i>	.	-	.	-	.	-	1	0.04%	<b>1</b>	<b>0.01%</b>
<i>Gangrene</i>	.	-	.	-	.	-	1	0.04%	<b>1</b>	<b>0.01%</b>
<i>Maceration</i>	.	-	.	-	.	-	1	0.04%	<b>1</b>	<b>0.01%</b>
<i>Inconvenient</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Erysipelas</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Eczema</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Dermatitis</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Inflammation</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Weep</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Systemma</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Pinch</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Stabbing</i>	1	0.01%	.	-	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Tickle</i>	.	-	1	0.07%	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Hyperkeratosis</i>	.	-	1	0.07%	.	-	.	-	<b>1</b>	<b>0.01%</b>
<i>Others</i>	3	0.04%	.	-	2	0.31%	.	-	<b>5</b>	<b>0.04%</b>
<i>Not specified</i>	20	0.27%	3	0.21%	4	0.62%	5	0.21%	<b>32</b>	<b>0.27%</b>

## **6 Global opinion of investigators**

Overall assessment of investigators at last visit was scored as “excellent” in the majority of cases, the best scores being obtained for the category “Other wounds”.

“Tolerability” and “Treatment of infection” were the item with the highest percentage of responses graded as excellent.

**Table 11. Overall assessment graded as Excellent**

	<i>Pressure sores</i>	<i>Leg ulcers</i>	<i>Diabetic foot</i>	<i>Other wounds</i>
<i>Treatment of infection</i>	57%	53%	60%	70%
<i>Healing</i>	51%	50%	56%	65%
<i>Tolerability</i>	64%	63%	70%	73%
<i>Dressing handling</i>	54%	55%	59%	65%
<i>Dressing compliance</i>	54%	55%	55%	67%

When compared to previous treatment, investigators considered Actisorb as better or much better in more than 73% of the cases. “Treatment of infection” and “Healing” were the item with the best response rates.

**Table 12. Overall assessment graded as “better” or “much better” compared to previous treatment**

	<i>Pressure sores</i>	<i>Leg ulcers</i>	<i>Diabetic foot</i>	<i>Other wounds</i>
<i>Treatment of infection</i>	89%	86%	88%	87%
<i>Healing</i>	87%	85%	87%	79%
<i>Tolerability</i>	72%	69%	71%	73%
<i>Dressing handling</i>	76%	77%	76%	76%
<i>Dressing compliance</i>	75%	73%	67%	79%

As a consequence of these high level of satisfaction, almost all investigators concluded they will include Actisorb in their therapeutic scheme.

## 7 Conclusion

The vast majority of the chronic wounds included in these series of post-marketing surveys were difficult wounds. They were strongly exsudative, covered with abundant necrotic tissues and fibrinous deposits. More importantly signs of infection were present in greater than 60% of the cases. Accordingly 38% of these wounds were treated with local antibiotics and 13% with systemic antibiotherapy, a management that might be regarded as not fully appropriate. After switching to Actisorb a dramatic improvement of wound status was observed. More than 90% of wounds improved and the overall healing rate was 41%. All characteristics of wounds improved and as high as 80% of these lesions did not required concomitant treatment in addition to Actisorb.

Dressing tolerability was excellent with a prevalence of local side-effects (dressing related or not) of 3.0% and a drop-out rate due to dressing-related reasons of 3.6%.

The overall opinion of investigators strongly favored Actisorb use and almost all of the participants included Actisorb in their usual therapeutic scheme.

In conclusion, this post-marketing survey has unambiguously confirmed the very highly favorable benefit/risk ratio of Actisorb when used in usual medical practice on various difficult wounds with delayed healing. Apart from its efficacy property and excellent tolerability, one of the main advantage of this dressing resides in its potential capacity to limit local use of antibiotics/antiseptics of yet unproved clinical interest in such situations.

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