

# Open, non-comparative, multicentre investigation exploring the tolerance of an absorbent foam dressing containing silver used in chronic wounds.

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## Introduction

This is an explorative clinical investigation evaluating an antimicrobial soft silicone foam dressing containing silver sulphate. The absorbent polyurethane foam (Mepilex Ag) has an outer film, which is vapour permeable and waterproof. The silver ions are hydro activated in the presence of fluid or wound exudate. Silver has been shown to be effective against a broad range of aerobic, anaerobic, Gram-positive and Gram-negative bacteria as well as fungi and viruses. The combination of silver with an absorptive dressing is a method to control the polymicrobial wound bioburden. Control of the bioburden in the wound offers the possibility to enhance healing.

## Aim

The primary objective was to investigate the tolerance of the antimicrobial soft silicone foam dressing in chronic wounds.

The secondary objectives were to investigate the performance of the wound dressing and to follow the wound status.

## Methods

The study was done in four centres enrolling patients with chronic ulcers. The study was designed as an open non-comparative and prospective study. The study period was 4 weeks. The aetiology of the ulcers was either venous leg ulcers or venous leg ulcers with a mixed arterial / venous aetiology. Diabetic foot ulcers were also included. Adult patients of both genders with a maximum ulcer size of 200 cm<sup>2</sup>, an ulcer age of at least 6 weeks and an ABI of more than 0.5 could be enrolled. Patients with debridement and/or topical treatment with antimicrobials within 7 days prior to study start were excluded. Patients with necrosis of any type or use of steroids were also excluded. Descriptive statistics based on median values and min – max is presented.

## Results

18 patients, 12 males, with normal body stature were included.

The wounds were of venous aetiology in 11 patients, mixed in 4 and diabetic foot ulcers in 3. The median age of the wounds was 1.8 (0.2 – 8.0) years. The median ABI was 1.0 (0.6 – 1.0).

Table 1 presents the performance variables and tolerance.

		Baseline Visit 1 n=18	Week 4 Final visit n=18
Healthy / Intact	Actual value	5 (27.8%)	9 (50%)
Viable tissue (%)	Actual value	75.0 (10.0-100.0)	85.0 (25.0-100.0)
Wound size [Tracing, cm <sup>2</sup> ]	Actual value	6.3 (2.4 - 39.0)	2.9 (0.0 - 68.2)
	% change from Baseline		-29.6 (0.0 - 68.2)
Inflammation	Actual value	3 (16.7%)	0 (0%)
Odour	Actual value	1 (5.6%)	0 (0%)
Debridement	Actual value	10 (55.6%)	8 (44.4%)
Exudate level:	Actual value		3 (16.7%)
None		0 (0%)	
Low		8 (44.4%)	
Moderate		5 (27.8%)	
High		5 (27.8%)	
Exudate type:	Actual value		11 (68.8%)
Clear		9 (50.0%)	2 (11.1%)
Yellow / green		6 (33.3%)	3 (16.7%)
Brown / blood		2 (11.1%)	0 (0%)
Black / liquid		0 (0%)	1 (6.3%)
Other		1 (5.6%)	

The performance and tolerance data suggests (see table 1)

- increase in the number of healthy wounds
- increase in viable tissue from 75 to 85%
- reduction of the wound size by approximately 30%
- reduction of the number of patients with wounds with inflammation
- reduction in the number of patients with highly exuding wounds

AEs reported in the investigation were 8 in total (see table 2).

Table 2. AEs reported.

The AE data suggest (see table 2)

Patient	AE	SAE	ADE	Ongoing at final visit
201	Bullous Pemphigoid			X
103	Ulcer worse		X	
104	Eczema		X	
306	Vasculitis		X	
204	Death	X		
304	Pneumonia	X		X
304	Sepsis	X		X
305	Heart insufficiency	X		

- The four serious AEs were not considered related to the wound treatment.
- The three AEs considered related to the treatment (ADEs) were;

ulcer worse, eczema and vasculitis.

- All AEs were given adequate treatment and / or medication.

Three of the AEs reported were still ongoing at the last visit in the investigation.

Table 3. Pain recorded by means of the VAS-scale.

		Baseline Visit 1 n=18	Week 4 Final visit n=18
At dressing removal	Actual value	1.0 (0.0 - 22.0)	0.0 (0.0 - 23.0)
	Change from Baseline		0.0 (-10.0 - 1.0)
After application of new dressing	Actual value	1.0 (0.0 - 60.0)	1.0 (0.0 - 47.0)
	Change from Baseline		0.0 (-13.0 - 2.0)
Since last visit	Actual value	1.5 (0.0 - 80.0)	2.0 (0.0 - 41.0)

The data concerning pain suggests (see table 3)

- the degree of pain was low at Baseline
- the degree of pain did not change over time
  - at or after dressing changes
  - between visits

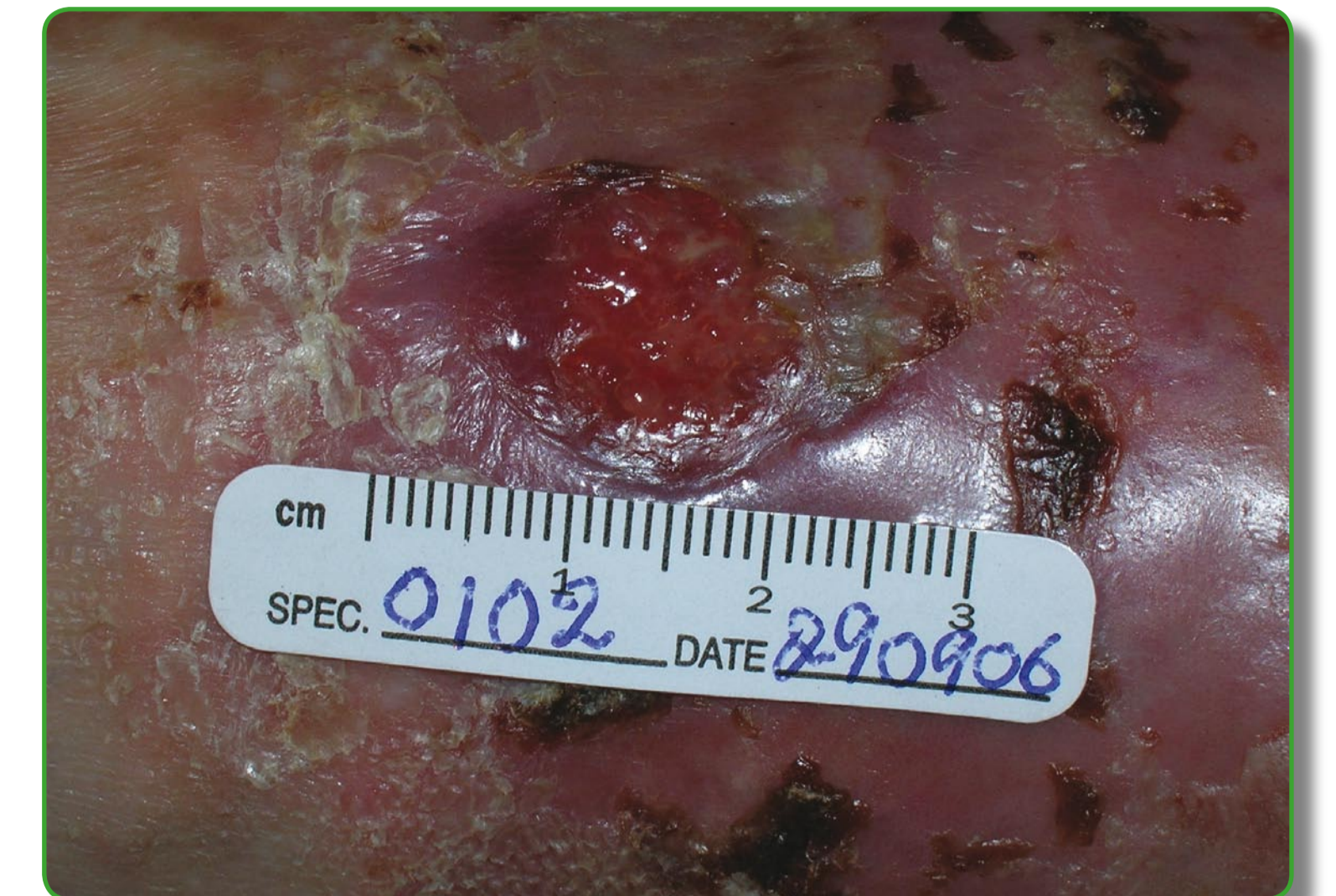
## Conclusions

The data in this exploratory study evaluating Mepilex Ag suggests

- Increase in the number of healthy wounds
- 30% reduction in wound size
- Increase in viable tissue
- Reduction of inflammation
- Reduction highly exuding wounds
- Low levels of pain preserved
- Few AEs related to the treatment

It may be concluded that Mepilex Ag was well tolerated and effective in the current investigation in elderly patients. The result in the current investigation is promising and warrants further evaluation of Mepilex Ag.

Baseline visit



Patient 102, a male patient with a venous leg ulcer of 3 months duration. Erythema and redness present. Wound size 2.4 cm<sup>2</sup>.

Final visit



Patient 102, after 4 weeks treatment with Mepilex Ag the patient is healed and the surrounding skin looks healthy

