

# Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic non-commercial multicentre randomised open label parallel group medical device trial.

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# Introduction

## What's already known?

- ▶ The incidence of hospital-acquired pressure ulcers (HA-PU) remains high despite the implementation of best practice recommendations.<sup>1</sup>
- ▶ A systematic review (2020), presents the pooled prevalence of HA-PU (n=1,366,848) as **12.8%**, a pooled incidence rate of 5.4 per 10 000 patient-days (n=681,885) and pooled rate of HA-PU (n=1,893,593) as **8.4%**.<sup>2</sup>

1. Demarré L, Verhaeghe S, Annemans L, Van Hecke A, Grypdonck M, Beeckman D. The cost of pressure ulcer prevention and treatment in hospitals and nursing homes in Flanders: A cost-of-illness study. *Int J Nurs Stud* 2015; 52(7): 1166–1179.

2. Li Z, Lin F, Thalib L, Chaboyer, W. Global prevalence and incidence of pressure injuries in hospitalised adult patients: A systematic review and meta-analysis. *Int J Nurs Stud* 2020; 105(103546).

# Introduction

## What's already known?

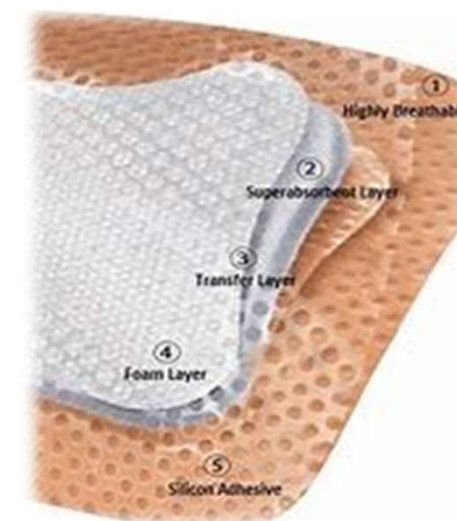
- The concept of using silicone foam dressings as an *additional* prophylactic strategy in PU prevention has been investigated in previous studies,\* however with some limitations.
- At the time of publication there were no **non-commercial, multicenter, multi-skin site, large scale** results available to test the efficacy of using these dressings as adjuvant prophylactic therapy in further preventing HA-PUs.

\* 5 systematic reviews; 7 RCTs – references available on request

# Introduction

**Silicone foam dressings** (depending on their construction),

- ▶ redistribute pressure over larger areas,
- ▶ mitigate external shearing forces on the skin (multiple layers),
- ▶ might assist with maintaining microclimate for the skin to function normally (foam structure/layers and film breathability)
- ▶ remove gently from the skin, and can be repositioned after visualising the skin (silicone-based adhesive)



# Objective

## Primary endpoint

Determine if silicone adhesive multilayer foam dressings applied to the sacrum, heels, and greater trochanters in *addition* to standard prevention, reduce PU incidence category 2 or worse compared to standard prevention alone.

Risk assessment

Skin assessment

Repositioning

Heel offloading

Nutrition

Skin care

# Methods

## Design

- ▶ Multi-centre, randomised controlled, open label, parallel group medical device trial
- ▶ February – December 2018
- ▶ Pragmatic vs. exploratory

## Setting

- ▶ Eight hospitals in Belgium (university/teaching and regional)
- ▶ ICU and non-ICU (geriatrics, surgery, internal medicine, rehabilitation)

# Methods

## Participants

- ▶ Patients, > 18 years old, at risk for PU development (Braden score < 17)
- ▶ Hospitalised within the previous 48 hours
- ▶ No pre-existing PU at the sacral area or at least 3 of the 4 body sites accessible to observe
- ▶ No clinically relevant incontinence-associated dermatitis



# Methods

## Intervention

- ▶ Patients were centrally randomised to study groups based on a 1:1:1 allocation
  - ▶ The control group (n=546) → Standard of care
  - ▶ Experimental group 1: (n=542)
  - ▶ Experimental group 2 (n=545)
- } Treatment group



# Results

# BJD

- ▶ In the intention-to-treat population (n=1 605);
  - ▶ 4.8% developed a new PU category 2 or worse.
  - ▶ **4.0%** developed a PU category 2 or worse in the **treatment group**,
  - ▶ **6.3%** in the **control group**.
  - ▶ Statistically significant risk reduction (**36%**) to develop a new PU in the treatment group
  - ▶ NNT is 43

	Experimental n/N (%)	Standard of Care n/N (%)	RR* (95% CI)	P value
<b>Overall</b>	43/1066 (4.0)	34/539 (6.3)	0.64 (0.41-0.99)	0.04
<b>Body site</b>				
Sacrum	30/1062 (2.8)	26/539 (4.8)	0.59 (0.35-0.98)	0.04
Any heel	15/1063 (1.4)	10/538 (1.9)	0.76 (0.34-1.68)	0.49
Any trochanter	1/1065 (0.1)	0/539 (0)	n/a	n/a

RR\* refers to Standard of Care group

n/a: not applicable

- ▶ **Sacral pressure ulcers** were observed in 2.8% in the treatment group and 4.8% in the control group (RR=0.59, 95% CI 0.35-0.98, P=.04). The risk to develop a new PU on the sacrum was statistically significantly reduced by 41% in the treatment group (RR=0.59, 95% CI 0.35-0.98, P=.04)
- ▶ **Heel pressure ulcers** occurred in 1.4% and 1.9% of patients in the treatment and control group respectively - no statistical difference (RR=0.76, 95% CI 0.34-1.68, P=.49).
- ▶ One patient (0.1%) developed a pressure ulcer on the **trochanter**.

# Results

# BJD

- ▶ No serious adverse device effects were reported,
- ▶ 33 adverse device effects (ADEs) in 28 patients
- ▶ 246 device deficiencies (DDs) in 97 patients
  - ▶ Two patient- fall incidents, due to heel dressings being slippery on the floor, were reported.
  - ▶ Risk-benefit analysis for heel dressings?

	Treatment group		
	Allevyn Life® (N=539) n (%)	Mepilex Border® (N=538) n (%)	Total (N=1077) n (%)
<b>Device deficiency (DD)</b> (n DDs=246; n patients=97)			
All	168 (31.2)	78 (14.5)	246 (22.9)
Dressing layers separated	20 (3.7)	6 (1.1)	26 (2.4)
Poor adhesion / adhesion failure	75 (13.9)	52 (9.7)	127 (11.8)
Dressing causes floor to be slippery (increased fall risk)	19 (3.5)	7* (1.3)	26 (2.4)
Adhesive residue	10 (1.8)	0 (0.0)	10 (0.9)
Obstructs wearing footwear	1 (0.2)	2 (0.4)	3 (0.4)
Backing film/liner: adhesive transfer/ poor release	10 (1.9)	0 (0.0)	10 (0.9)
Rolled-up edges	33 (6.1)	11 (0.2)	44 (4.1)

# Conclusions

- ▶ Silicone adhesive multilayer foam dressings reduce the incidence of sacral pressure ulcers in addition to standard of care.

# Conclusions

- ▶ The current standard guidelines for PU prevention remain the cornerstone of prevention.
- ▶ New protocols should stress the importance of
  - ▶ Education
  - ▶ Daily assessment underneath the dressing, and
  - ▶ Monitoring of the adherence to the protocol

Future  
research:  
Health-  
economic  
analysis

# Conclusions

## What does this study add?

- ▶ This study was the first and unique:
  - ▶ Multicenter (ICU and non-ICU)
  - ▶ Multi-skin site (sacrum, heels and greater trochanters)
  - ▶ Large scale (n=1633)
  - ▶ Non-commercial

Changing  
clinical  
practice

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Thank you