

Summary report:

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

**Authors:** Beeckman, D., Fourie, A., Raepsaet, C., Van Damme, N., Savoye, I., Harrison, J., Vrijens, F., Hulstaert, F. British Journal of Dermatology. 2020 Nov. Available at: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjd.19689>

### Study aim:

To determine if silicone adhesive multilayer foam dressings applied to the sacrum, heels and greater trochanter in addition to standard prevention reduce pressure ulcer incidence (category 2 or worse) compared to standard pressure ulcer prevention alone.

### Study design and methodology:

A multicentre, randomised controlled, open label, parallel group medical device trial was performed in 8 hospitals in Belgium (12.4 % of patients from intensive care unit (ICU) and 87.5% from non-ICU) setting. Patients were randomly allocated to three study arms based on a 1:1:1 allocation. Maximum treatment duration was 14 days.

#### Control group

(n=546)

Standard pressure ulcer prevention strategies as described in the hospital protocol. No silicone adhesive multilayer dressings applied.

#### Experimental group\* 1 (n=542)

Standard prevention strategies PLUS Allevyn™ Life, Allevyn™ Life Sacrum and Allevyn™ Life Heel (Smith+Nephew) dressings applied to the greater trochanters, sacrum and heels.



#### Experimental group\* 2 (n=545)

Standard prevention strategies PLUS Mepilex® Border, Mepilex® Border Sacrum and Mepilex® Border Heel (Mölnlycke Health Care) dressings applied to the greater trochanters, sacrum and heels.



\*Experimental groups 1 and 2 were pooled in the analysis as the treatment group

### Results:

# 36%

relative reduction in pressure ulcers with use of dressings (p=0.04)

#### Pressure ulcer incidence:

**Control group 6.3% Treatment group 4.0%**

There were no significant differences reported between the 2 experimental groups in terms of pressure ulcer reduction but the study was not designed to show this.

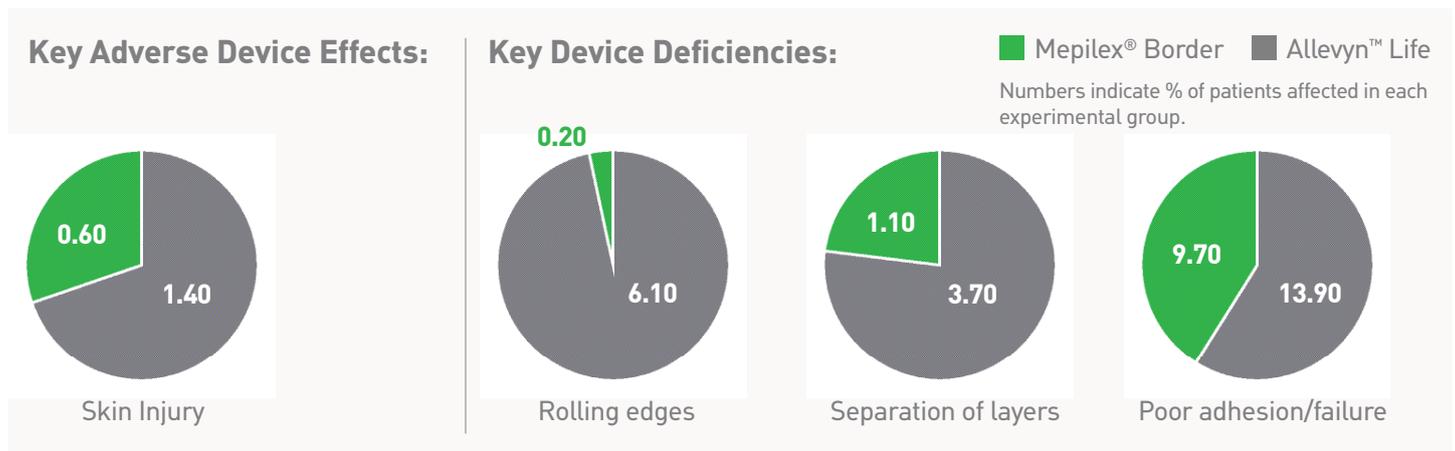
**However** differences were observed between the two dressing groups in the number of Adverse Device Effects and Device Deficiencies – see over for details

Fewer adverse device effects and device deficiencies were observed with Mepilex® Border dressings.

|                        | Total              | Allevyn™ Life | Mepilex® Border |
|------------------------|--------------------|---------------|-----------------|
| Adverse device effects | 33 in 28 patients  | 3.9% (n=21)   | 2.2% (n=12)     |
| Device deficiencies    | 246 in 97 patients | 31.2% (n=168) | 14.5% (n=78)    |

# Adverse Device Effects and Device Deficiencies

See below for examples of differences reported in the study. For full details please refer to the full publication.



## Conclusions:

The use of silicone adhesive multilayer foam dressings for PU prevention at the sacrum, heels and trochanters significantly decreased the incidence of PUs of category 2 or worse from 6.3% to 4.0% in hospitalised at-risk patients. The results show a decrease in PUs of category 2 or worse for the sacrum, but no statistically significant effect for the heels. The incidence of PUs on trochanters was too low to identify any effect.

### Key points:

- This study was not designed to determine differences between the two dressing brands in terms of PU risk reduction.
- Results were only significant at the sacrum. No significant difference was seen at the heel and only one PU was observed at the greater trochanter so analysis was not possible..
- Fewer adverse device effects and device deficiencies were observed with the Mepilex Border dressings.

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