# Safety and comparative efficacy of a new fully-versatile negative pressure wound therapy (NPWT) integrated dressing against commercially available competitor: an in vivo and in vitro analysis

Rey Paglinawan<sup>1</sup>, Lydia Cannady<sup>2</sup>

# INTRODUCTION

Negative Pressure Wound Therapy (NPWT) is a widely used modality in wound management. A novel peel and stick NPWT dressing with silicone adhesive dressing A° was designed for use as part of a fully-versatile NPWT system, that can be used at varying pressure levels and modalities, either with or without wound filler and in wounds ranging from low to high levels of exudate. The novel dressing A° was compared to dressing Bb, a commercially available peel and stick silicone based dressing, for adhesion and skin friendliness.

## **METHODS**

**Animal model:** An ethics approved study (The Animal Ethics Council, Denmark [Rådet for Dyreforsøg]) using a porcine wound model was carried out. Göttingen minipigs were allowed to acclimatize to the housing conditions prior to all procedures. In total, 6 animals were anesthetized, shaved and scrubbed for surgery, where deep circular wounds were excised over the dorso-lateral area of both sides of the back of the animal (12 wounds per condition). The wounds were treated with two types of siliconized adhesive dressing coupled with NPWT, (1) a novel dressing A, set pressure –125 mmHg and (2) a commercially available dressing B, set pressure –80 mmHg. Dressing changes occurred at the end of the seventh day and wound reduction was measured on day eight. Wound surface area changes between day 1 and day 8 areas were compared using a t-test.

**Standard tissue adhesive test:** A standard test method to compare the adhesive strengths of the siliconized adhesives intended for use as wound adhesives was applied. Briefly, samples from both siliconized adhesives were placed on a substrate (roll machine), samples were then secured on tensile test instrument, followed by application of load to pull samples off test substrate at a constant rate according to test procedures. To test the possibility of dressing repositioning, a second peel test was performed. Upon completion of 1st peel, the adhesive sample is removed from the substrate and re-applied to new substrate, where the steps are repeated (dressing A, n=19; dressing B, n=9). The average load during displacement and peel strength (Tensometer) was then calculated.

### RESULTS

No adverse events were recorded and none of the wounds in any treatment group showed signs of inflammation, necrotic tissue formation, maceration, bruising or hypergranulation. The average difference between day 1 and day 8 was 110.0 mm<sup>2</sup>

for dressing B, and 255.5 mm² for dressing A (Figure A). The average difference of wound surface area reductions between dressings A and B was 145.5 mm² (95% confidence interval: 92.7; 198.3, p<0.001). The initial peel adhesion removal force for dressing A was 2.00 N/2.5 cm compared to dressing B at 1.17 N/2.5 cm. Only the novel dressing A maintained the 100% of the initial removal force after repositioning. After repositioning, dressing B removal force was 0.87 N/2.5 cm (Figure B).

# CONCLUSION

The novel NPWT dressing A is safe and effective for use in wound management as demonstrated by the in vivo analysis. Both silicone-based dressings were shown to be skin-friendly. Dressing A demonstrated a statistically significant (p<0.001) greater decrease in overall wound area compared to dressing B. Dressing A had a larger wound surface reduction of 33% compared to dressing B (17%). The novel dressing A in vitro peel adhesion analysis maintained 100% of its initial peel adhesion after repositioning where dressing B initial peel adhesion is 41.2% lower than dressing A and dressing B lost 25.6% of its initial tack after repositioning. The test observed that, unlike dressing B, dressing A was not compromised if the dressing needed to be repositioned.

#### **Affiliations**

1 Medela AG, Baar, Switzerland 2 Medela LLC, McHenry, IL, USA

#### **Product notation**

a Siliconized adhesive dressing; Invia Liberty™ NPWT system, Medela AG
b PICO™, Smith & Nephew

#### **Trademarks**

Medela, Invia and Invia Liberty are registered in the U.S. Patent and Trademark Office and elsewhere. PICO is a trademark of Smith & Nephew.

## Acknowledgements

The support of Medela AG (Lättichstrasse 4b, 6340 Baar, Switzerland) for this project is gratefully acknowledged.

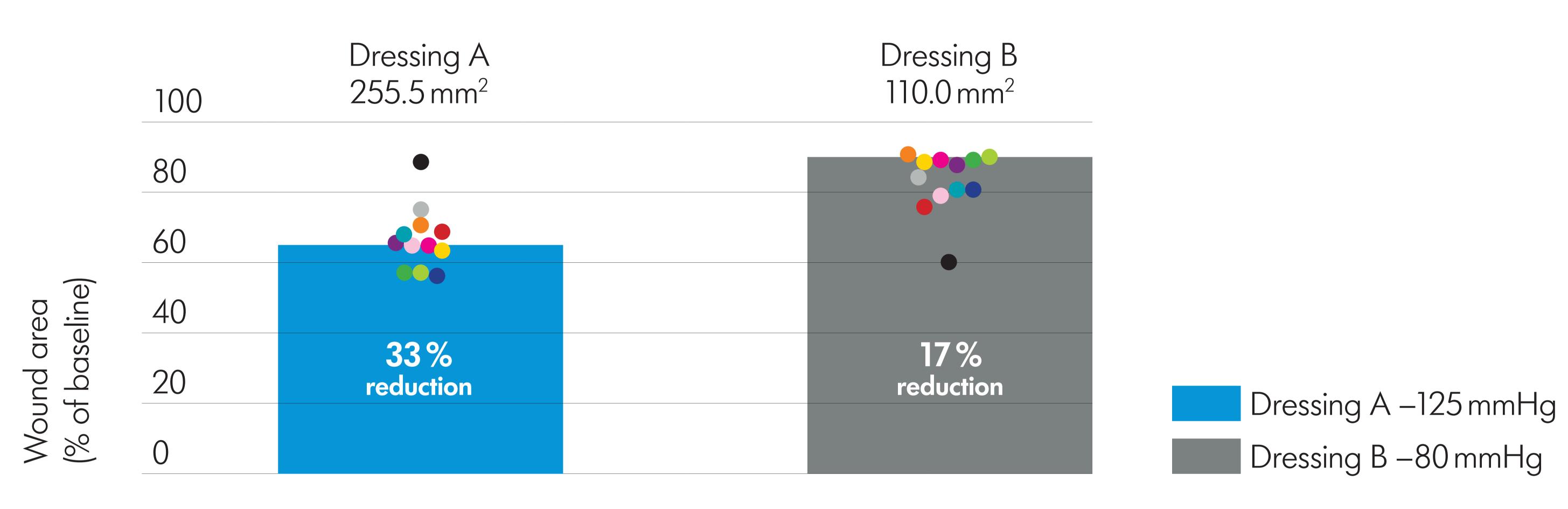
#### Correspondence

rey.paglinawan@medela.com

Presented at the 36th Annual Symposium on Advanced Wound Care (SAWC) Spring, April 26–30, 2023, National Harbor, MD, USA

# FIGURE A: WOUND AREA % REDUCTION





Dressing A statistically greater decrease in overall wound area versus dressing B, with dressing A having larger wound reductions between 92.7 to 198.3 mm<sup>2</sup> versus dressing B (p<0.001). The colored dots represent individual wound surface reduction relative to baseline.

# FIGURE B: PEEL ADHESION STRENGTH TESTS

