

A randomized controlled study to evaluate the use of silicone dressings for the treatment of skin tears.

Kevin Woo¹ and Kimberly LeBlanc,² Poster presentation at SAWC Fall, 2020

1. RN, NSWOC, WOCC (C), FAPWCA, Associate Professor, School of Nursing/School of Rehabilitation Therapy, Queen's University, Kingston, Toronto, Canada.

2. RN, NSWOC, WOCC (C), IIWCC Chair, Wound Ostomy Continence Institute/Institut de l'Enseignement Pour Infirmières en Plaies, Stomies et Continence, Ottawa, Canada.

Why?

- To undertake the first randomized controlled trial to evaluate the use of soft silicone dressings to promote healing of skin tears.
- To compare the effectiveness of soft silicone dressings for the healing of skin tears with local best practices that do not include soft silicone dressings.

Research questions

1. Is there a difference in the proportion of complete healing between soft silicone dressings and non-soft silicone dressings for treatment of skin tears?
2. Is there a difference in healing rates between soft silicone dressings and non-soft silicone dressings for treatment of skin tears?

How?

Study design:

Randomized controlled prospective pragmatic clinical study.

- Adults ≥ 18 years (n=126).
- Male 44.4%, female 55.6%, mean age 82.9 (+/- 8 years; 45-102 y.o.).
- Long-term care facility and complex continuing care hospital in Ottawa and Toronto, Canada.

Products:

Treatment group (65 individuals)

Mepilex® Border Flex (soft silicone all-in-one foam dressing) for exudative Type 2 and Type 3 skin tears.
Mepitel® One (soft silicone wound contact layer) for Type 1 and Type 2 skin tears with minimal exudate.

Control group (61 individuals)

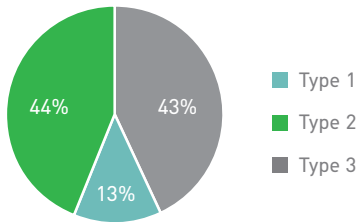
Alldress® (non-silicone foam dressing) for exudative Type 2 and Type 3 skin tears.
Telfa® (non-adherent non-silicone dressing) for Type 1 and Type 2 skin tears with minimal exudate.

Key measures:

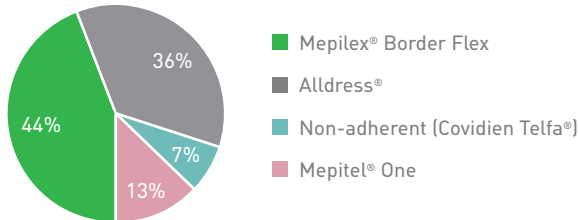
- All subjects were evaluated at week 0, week 1 and week 3 (i.e. at the end of the study).
- Weekly measurement of wound sizes and wound surface areas.
- Proportionate changes in mean surface area over the 3-week period.
- Photography of the wounds.
- Pain: Numeric Rating Scale (NRS) or Pain Assessment in Advanced Dementia (PAINAD) scale.
- Adverse events.

Key outcomes

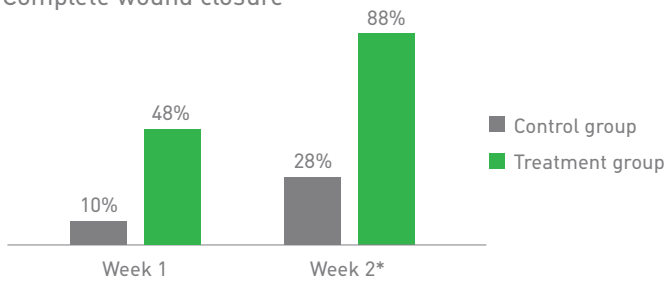
Skin tear classification



Product utilisation

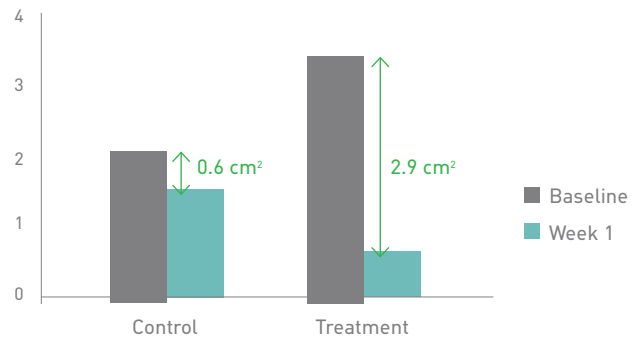


Complete wound closure



*Cumulative week 1 and 2

Mean wound surface area



Control (n=58): 2.1–1.5= 0.6 cm²

Treatment (n=64): 3.4–0.64= 2.9 cm²

t value = -3.04 (df=73.6); p=0.003

Skin tear healing time

95% Confidence Interval				
Group assignments	Time to heal (days)	Std Error	Lower	Upper
Control	20.000	.964	18.111	21.889
Silicone	8.615	.858	6.934	10.297
Overall	15.037	1.307	1.307	17.598

X² 16.516 p<.0001

- Mepitel® One showed clinical benefits in the management of Skin tears Type 1 & 2 and Mepilex® Border Flex in the management of Skin tears Type 2 & 3.
- Significantly greater reduction in wound surface area relative to baseline in Treatment group (2.9 cm²) compared to Control group (0.6 cm²) (p=0.003).

- 88% of patients achieved complete wound closure at week 2 in the Treatment group compared to 28% in the Control group.
- Skin tears in elderly patients (mean age 82.9) healed over 50% faster with soft silicone dressings compared with conventional non-adherent dressings (~8 days vs 20 days).

Investigator Conclusion

Results of this study suggest that silicone dressings are superior to non-silicone dressing for the management of skin tears. Full study results to be shared after the publication is available.

This summary has been compiled by the Medical and Economic Affairs Department of Mölnlycke Health Care as a service to healthcare professionals.

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