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

Kevin Woo[1] and Kimberly LeBlanc[2], Poster presentation at Wound Con Summer (virtual) conference, 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 randomised 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:

Randomised 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.

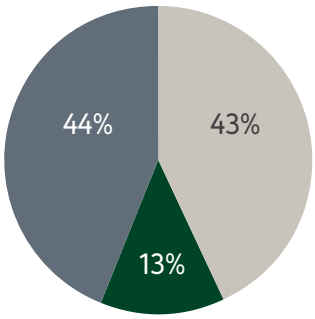
Key measures:

- 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.

Mölnlycke®

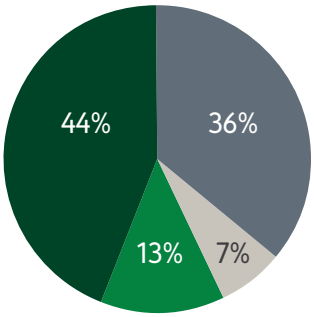
Key outcomes

Skin tear classification



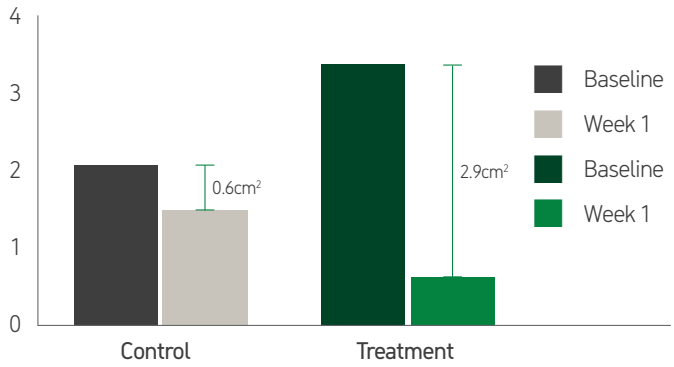
- Type 1
- Type 2
- Type 3

Product utilisation



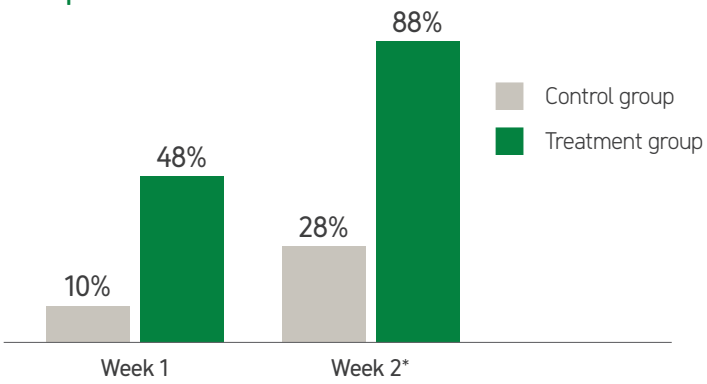
- Mepilex Border Flex
- Alldress
- Non-adherent (Covidien Telfa)
- Mepitel One

Mean wound surface area



Control (n=58): 2.1–1.5= 0.6cm²
Treatment (n=64): 3.4–0.64= 2.9cm²
t value = -3.04 (df=73.6); p=0.003

Complete wound closure



*Cumulative week 1 and 2

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

X^2 16.516 p<.0001

- **Mepitel One** showed clinical benefits in the treatment of skin tears **Type 1 and 2 and Mepilex Border Flex** in the treatment of skin tears **Type 2 and 3**.
- **Significantly greater reduction** in wound surface area relative to baseline in Treatment group (2.9cm²) compared to Control group (0.6cm²) (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)**.

Results of this study suggest that silicone dressings are superior (quicker complete wound closure and faster mean healing time) to non-silicone dressing for the treatment of skin tears.

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

Find out more at molnlycke.com

Mölnlycke Health Care AB, P.O. Box 6, Entreprenörsstråket 21, SE-431 21 Mölndal Sweden. Phone + 46 31 722 30 00.

Mölnlycke®