

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

Kevin Woo¹ and Kimberly LeBlanc², Poster presentation at Wound Con Summer (virtual) conference, 2020

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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 \geq 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.

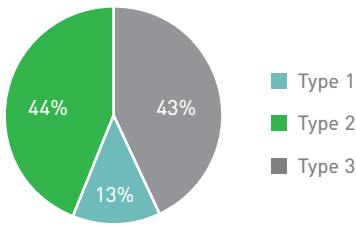
Telfa® (non-adherent non-silicone dressing) for Type 1 and Type 2 skin tears with minimal exudate.

Key measures:

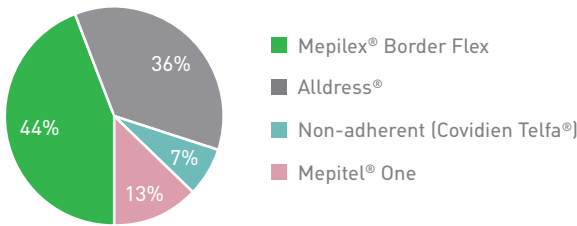
- All subjects were evaluated at week 0, week 1 and week 3 (i.e. at the end of the study).
- Weekly measurement of wound sizes and wound surface areas.
- Proportionate changes in mean surface area over the 3-week period.
- Photography of the wounds.
- Pain: Numeric Rating Scale (NRS) or Pain Assessment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

Key outcomes

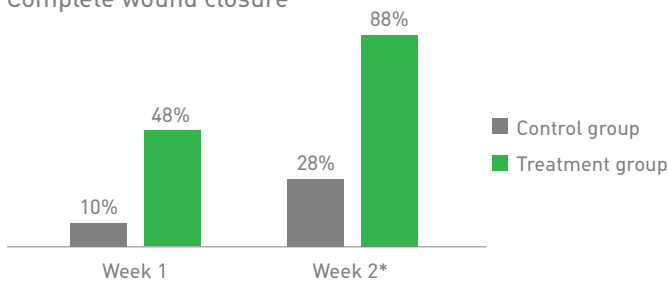
Skin tear classification



Product utilisation

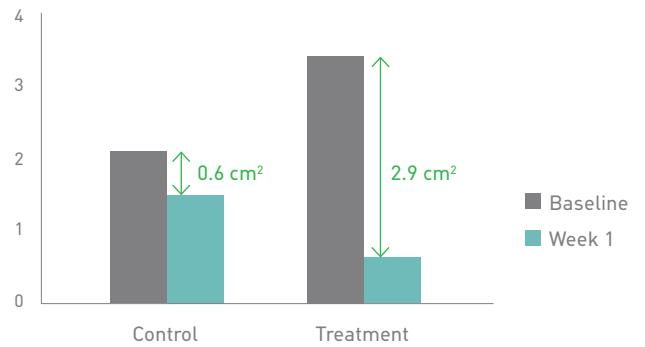


Complete wound closure



*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

Group assignments	Time to heal (days)	Std Error	95% Confidence Interval	
			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 treatment of Skin tears Type 1 & 2 and Mepilex® Border Flex in the treatment 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).

Conclusions

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. Full study results to be shared after the publication is available.

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