

LEVEL TWO - CLINICAL EVALUATION

A non-comparative multicentre clinical evaluation of a new hydropolymer adhesive dressing.

Taylor, A., Lane, C., Walsh, J., Whittaker, S., Ballard, K., Young, S.R. J Wound Care 1999, 8(10):489-492.

KEY POINTS

- A multicentre, non-comparative 4-week clinical trial, evaluating the performance of TIELLE Lite in the treatment of acute and chronic wounds, in 74 patients.
- TIELLE Lite performed extremely well with 98.4% of the dressings not adhering to the wound bed even in the presence of bleeding and/or low levels of exudate.
- TIELLE Lite was found to be comfortable, easy to remove, normally pain-free, and suitable for treatment of bleeding wounds or those with low levels of exudate.

STUDY OBJECTIVE

This study evaluates the performance of TIELLE Lite in acute and chronic wounds, in the presence of bleeding and/or low exudate, with respect to adherence to the wound bed.

METHODS

74 patients (75 wounds) were recruited in a multicentre, non-comparative 4-week clinical study, treating 32 chronic wounds and 43 acute wounds with TIELLE Lite.

Bleeding and/or low exudate wounds were included in this study, however wounds with moderate or high exudate levels were excluded.

Dressings were inspected daily, and changed when necessary (maximum 7 days).

Parameters measured at each dressing change were:

- Assessment of adherence
- Wound area
- Pain (on removal)
- Safety (adverse events)
- Patient assessment – comparison with previous dressings, ease of application and removal

RESULTS

Dressing adherence:

- A total of 244 dressings were used in this study and 240 (98.4%) did not adhere to the wound bed. Of the 4 incidences of adherence 3 were associated with acute wounds and 1 with chronic wounds.

Efficacy:

- 40 wounds healed during the study: 8 chronic and 32 acute wounds.
- A 42 +/- 20% reduction in the mean wound area for chronic wounds was observed after 4 weeks treatment

Clinician rating:

CLINICIAN RATINGS (FROM 158 DRESSING CHANGES)	
CRITERIA	PERCENTAGE
EASE OF REMOVAL	
Easy	84%
Minor difficulties	14%
Difficult	3%
LEAKAGE	
Not present	84%
Slight leakage	13%
Moderate leakage	3%
CLINICIAN RATINGS (FROM 170 WEEKLY ASSESSMENT)	
PAINLESS REMOVAL	84%
DEHYDRATION OF THE WOUND BED	1.2%

CONCLUSIONS

The primary outcome of this study demonstrated that 98.4% (240/244) of dressing changes did not adhere to the wound, even though 67% of wounds had blood present at baseline.

TIELLE Lite was considered relatively pain-free and easy to remove, correlating with low incidence of adherence to the wound bed.