

LEVEL ONE - RCT STUDY

A comparison of two dressings in the management of chronic wounds.

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KEY POINTS

- An open, 2-centre RCT in venous leg ulcers (n=100) and pressure ulcers (n=99), comparing TIELLE and GRANUFLEX* (a hydrocolloid dressing).
- TIELLE performed significantly better than GRANUFLEX with less instances of dressing leakage (p=0.007) and a reduction in odour noted (p=0.023).
- Significantly more leg ulcers treated with TIELLE reduced in wound area compared to GRANUFLEX (p=0.028). TIELLE was also considered more comfortable than GRANUFLEX (p=0.027).
- During the course of the study, GRANUFLEX was considered more difficult to remove in pressure sores (17%) compared to TIELLE (2%).
- Maceration was recorded in a small number of wounds treated with GRANUFLEX, compared to none for TIELLE.

STUDY OBJECTIVE

To evaluate the performance of 2 dressings, GRANUFLEX and TIELLE, in the management of leg ulcers and pressure sores, comparing wear time, ease of application and removal, and management of exudate.

METHODS

TIELLE is a hydropolymer dressing consisting of a polyurethane backing material, a polyurethane adhesive and an absorbent island of a hydrophilic polyurethane foam. A non-woven fabric layer between these components facilitates lateral dispersion of exudate and maximizes the dressings fluid handling capacity.

GRANUFLEX (a hydrocolloid dressing) is a thin polyurethane foam sheet with an adhesive polymer matrix containing gel-forming agents gelatin, pectin and sodium carboxymethyl cellulose.

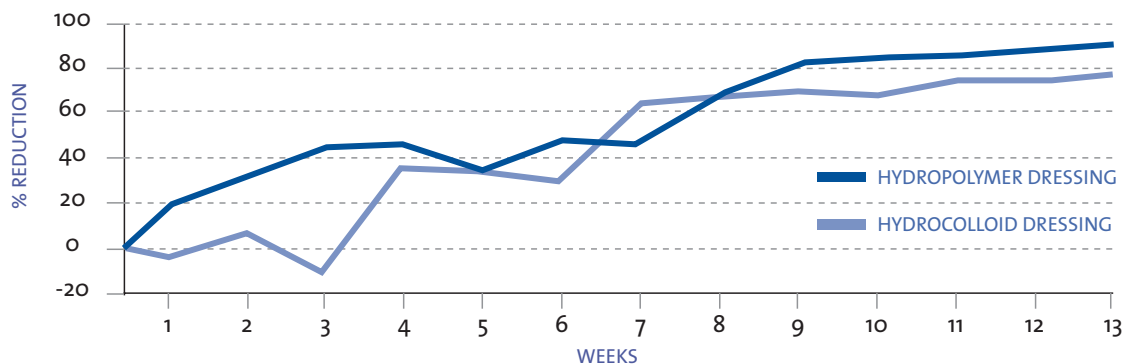
An open randomised controlled, 2-centre comparative study, involving 199 patients was carried out in the community.

- Venous leg ulcers (VLU; 100 patients), that had a maximum diameter of 8cm and a ABPI >0.8, were treated for 13 weeks with dressing & compression
- Pressure sores (PS; 99 patients), grade 2/3, & less than 10mm deep were treated for 6 weeks with dressing and appropriate pressure-relieving devices
- At dressing change length of time dressing had been in place, ease of removal, pain / discomfort, presence of odour, an estimate of exudate production & evidence of leakage was recorded.

RESULTS

Significantly more leg ulcers treated with TIELLE (44/49, 90%) reduced in area, compared to GRANUFLEX (34/47, 72%), $p=0.028$. Also, the reduction in wound size was faster in the TIELLE treated wounds, however this difference was not significant.

MEAN PERCENTAGE REDUCTION IN LEG ULCER SIZE



While mean time until first dressing change was similar for both dressings, significantly more patients in the GRANUFLEX group had dressings removed because of leakage; VLU patients, GRANUFLEX $n=27$, TIELLE $n=7$, ($p<0.0001$) and similarly for PS patients, GRANUFLEX $n=15$, TIELLE $n=4$, ($p=0.007$).

No maceration was recorded in the TIELLE treated group, however maceration was noted in a small number of wounds treated with GRANUFLEX. In only 2 patients was adherence of the hydropolymer to the wound surface noted.

Initially both dressings were recorded as easy to remove, however during course of treatment GRANUFLEX was rated as difficult to remove in the PS group, (85/509, 17% versus TIELLE, 11/537, 2%).

TIELLE treated wounds produced significantly less odour (no odour versus otherwise, $p=0.023$) and were more comfortable (comfortable versus otherwise, $p=0.023$).

CONCLUSIONS

Statistically significant differences in the performance of the dressings were detected, with TIELLE dressing performing better than GRANUFLEX; patients treated with TIELLE experienced significantly less instances of leakage, reduced odour and found the dressing more comfortable than GRANUFLEX.