

# TIELLE®

## LEVEL TWO - CLINICAL EVALUATION

### Evaluation of TIELLE® hydropolymer dressings in the management of chronic exudating wounds in primary care

Diehm C., Lawall, H. Int. Wound J. 2005, 2(1):26-35.

#### KEY POINTS

- A summary of 3 prospective multicentre, open-label, single arm studies evaluating the use of TIELLE® in a total of 6993 patients with venous leg ulcers, pressure sores, diabetic foot disease and other wounds over an observation period of 4 or 12 weeks
- TIELLE® dressing was clinically efficacious in all wound types and improved the condition of the wound in 95% of cases within 4 weeks
- The frequency of dressing change was reduced from 5 to 3 per week with TIELLE® compared to the preceding therapy
- TIELLE® provides a cost-effective and safe dressing for the management of chronic exudating wounds, in primary care

#### STUDY OBJECTIVE

To assess TIELLE® dressings in the treatment of chronic exudating wounds of all types, with regards efficacy, tolerability and ease of use.

#### METHODS

Data was compiled from 3 prospective, multicentre, open-label, single arm, phase IV studies conducted between 1996 and 2000, with a total of 6993 patients. All 3 studies were included in a pooled analysis

- 2 studies monitored dressing use over 4 weeks, (2770 & 1868 patients)
- 1 study over 12 weeks (2355 patients)

All patients were treated with TIELLE® hydropolymer dressing.

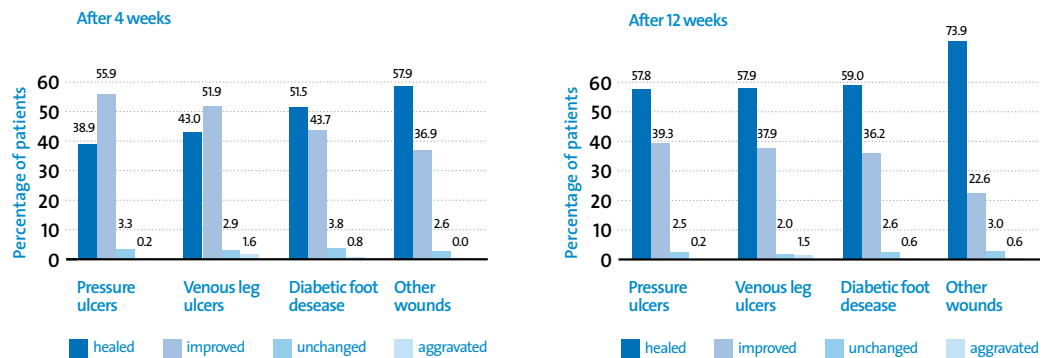
The total 6993 patients included 59.8% venous leg ulcers, 26.6% pressure sores, 9.8% diabetic foot ulcers and 5.1% other wound types (traumatic & post-operative).

The mean wound age prior to enrollment was 7.8 months, with 49.2% showing signs of infection and 57.4% with moderate / high levels of exudate.

## RESULTS

### TIELLE® had an efficacious effect on wound healing

- At 4 weeks 43.3% wounds healed & 51.6% were improved (combined 94.9%)
- At 12 weeks 59.1% wound healed & 36.9% improved (combined 96%)
- Wound area was reduced by 78.2% (wk4) and 85.1% (wk12)
- The frequency of infection decreased from 49.2% to 5.5% (wk4) and 3.4% (wk12)
- Exudate management improved – strong/medium exudate levels in 57.4% wounds reduced to 6.7% by wk4 and 4.0% by wk12



### Physicians' ratings

- Cosmetic results were excellent or good in 96.9% of healed wounds
- Efficacy was assessed as 59% much better and 33.5% better than previous treatment (combined 92.5%)
- Worse efficacy was only noted in 0.9% patients

### Safety

- Adverse events were rare and only occurred in 2.9% patients.
- Only 4.5% patients withdrew from the studies prematurely; 0.5% insufficient efficacy, 0.5% due to intolerance, 0.4% due to worsening of the wound, and 0.4% died during the study (not related to TIELLE®)

### Health economics

- Dressing frequency was reduced by 43% compared to previous treatment, an effect, which was attributed to the enhanced ability of TIELLE® to handle exudate, and may result in a cost saving

## CONCLUSIONS

- 95% patients benefited from the use of TIELLE® dressings in terms of efficacy, independent of wound type
- 92.5% physicians rated the overall performance of TIELLE® as superior to previous treatments
- 96.1% physicians wanted to include TIELLE® as part of their standard therapy for treatment of chronic wounds, independent of wound type
- Patients' quality of life was improved by high tolerability, easy handling and low rate of adverse events
- TIELLE® may also be cost saving because of longer wear time