An open, prospective clinical in-market evaluation of a modern silicone foam dressing

Dr. Roland Becker, Prof. Dr. Heinz Janßen

Background

Chronic wounds represent nowadays a widespread and very cost-intensive problem. An adequate care provision of chronic wounds is therefore a big challenge for the patients themselves on the one hand and for the society as a whole, particularly against the background of an ageing society and increasing cost pressure. The relevance of this issue appears even more pronounced if chronic wounds are regarded as a major cause of morbidity in the population and if the impact of chronic leg ulceration on the patients' quality of life is taken into account[1].

Aim

Only a small amount of clinical data currently exists on the product in use so a large study across various wound types would match with standard clinical practice. The primary objective was to assess overall acceptability of the dressings for their indicated uses. Secondary objectives were to assess the foam dressing in terms of dressing retention, performance characteristics and change in wound condition.

Methods

An open, prospective clinical in-market evaluation of a modern silicone foam dressing* was conducted in 2010. For this purpose, a questionnaire including all clinically relevant parameters was developed and applied at two points in time. A total of 523 patients were recruited in Germany with a mean age of 67 years (range 20-99). The wound types treated were 36% leg ulcers, 15% pressure ulcers, 14% diabetic foot syndrome, 14% traumatic wound, 12% surgical wound, 4% burns and 5% other wounds. The following figure illustrates the overall study design.

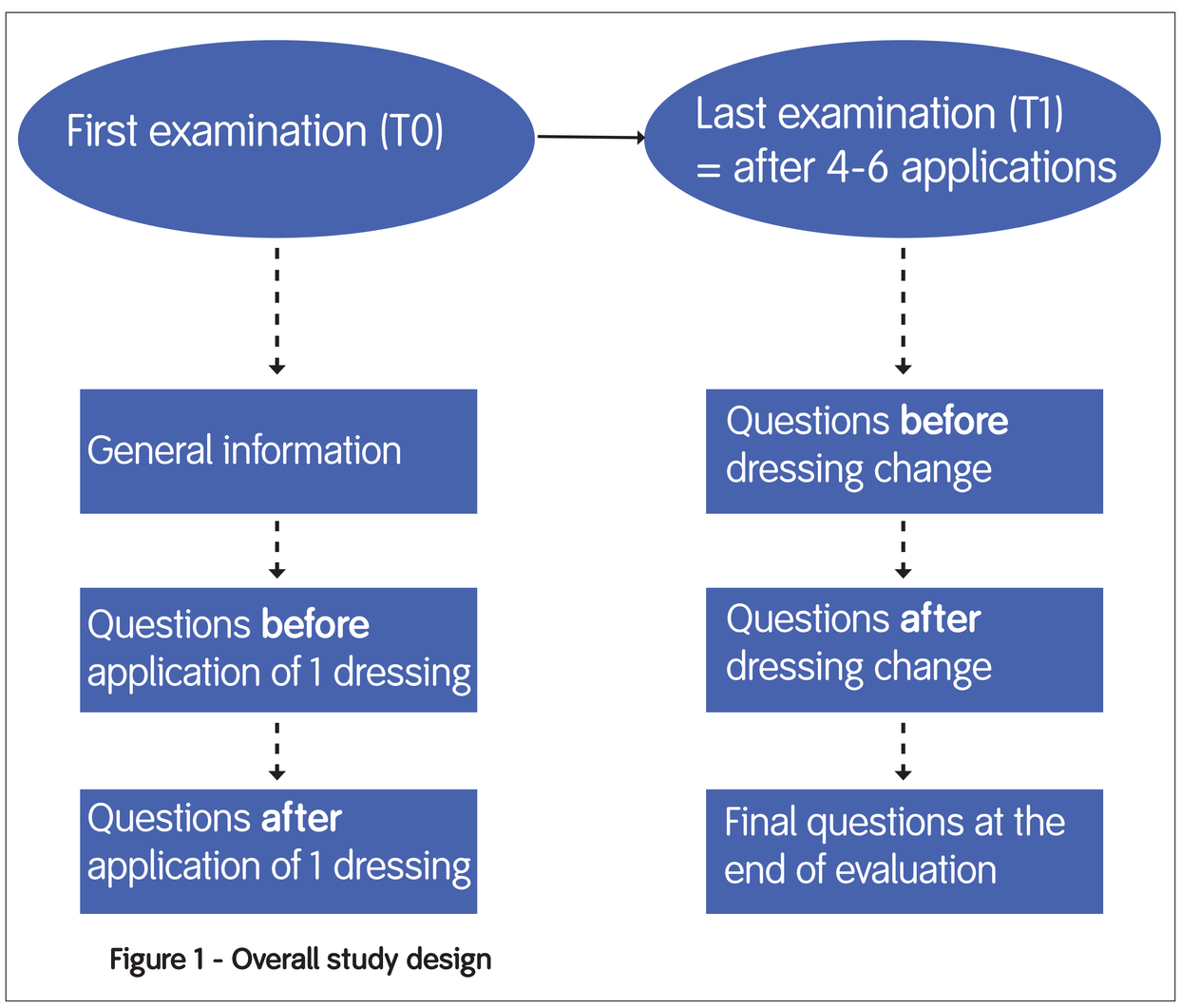


Figure 1 - Overall study design

The panel data was derived from a survey conducted with General Practitioners. The inclusion criteria for the study was an age > 18 years, no pregnancy at start of study and the existence of an exuding wound (acute or chronic). Exclusion criteria was a known allergy against one or various elements of product, a known history of lack of compliance and/or inclusion more than once in the evaluation.

The scheme of analyses was as follows:

a) at the begin of study (T0)
b) at the end of study (T1)
c) comparative analyses from T0 to T1 and
d) analyses at the end of evaluation

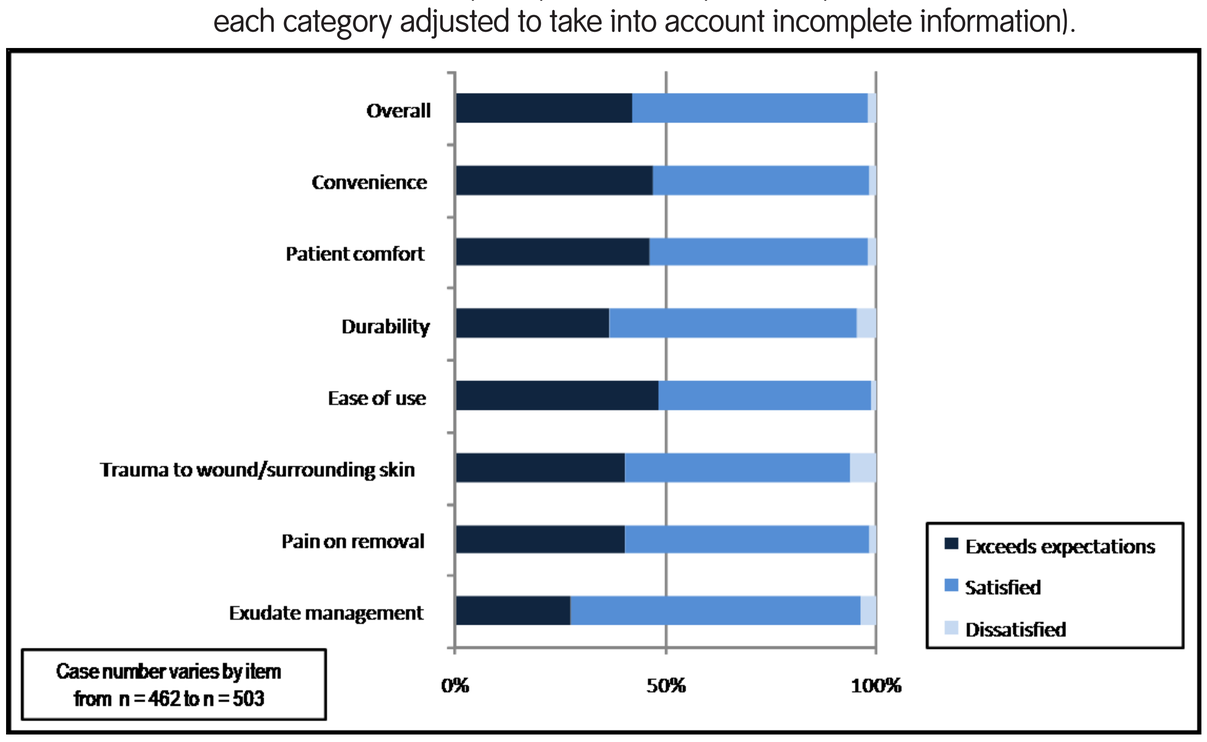
The number of participating practitioners was n = 143.
The number of evaluated patients was n = 523

Results

The performance characteristics of the foam dressings include:

1) In 94% of patients, clinician's rated the dressing as acceptable for the indication treated
2) For 96% of patients, the clinician was satisfied with exudate handling of the dressing
3) No pain on dressing removal with 71% patients
4) Conformability on application was rated as good for 89% of patients
5) Comfortable during wear for 96% patients
6) Easy to apply (98% patients)
7) Easy to remove (100% patients)

The following figure gives an overview on the results of the level of satisfaction stated by the practitioners per each patient (the numbers in each category adjusted to take into account incomplete information).



The vast majority of all participating practitioners was satisfied or stated that the dressing even exceeded their expectations (Overall mean value = 1.62).
The usage of the modern silicone foam dressing can all in all from a clinical perspective be recommended for all wound types specified in the study.
The usage of the modern silicone foam dressing can, however, not just clinically be recommended, but also seems from the patients` perspective to have been acceptable or very acceptable. Given that treatment is undertaken with the right co-ordinated approach, the usage of this modern wound dressing can lead to:

- clinically highly relevant good outcome measures (wound size reduction, improved wound healing rate, reduction of exudate level)
- an increase in patient quality of life (reduced wound pain, less trauma to wound/surrounding skin at dressing change, leading itself to higher concordance) and finally (as an effect) to
- substantial economic savings in the long-run (especially throughout faster healing and therefore shorter patient stays)

Conclusions

The data suggests that the dressing is considered as acceptable in the management of a variety of wound types. Other important influencing factors certainly have to be – given the complexity of the wound healing process – accounted for, too. Relevant factors are e.g. additional measures towards the improvement of patients` concordance/compliance, education programs in order to ensure that modern wound care products are adequately used and a functioning integration and cooperation of all relevant factors.

Reference
1. Posnett, J., Franks, P.J, (2008) The burden of chronic wounds in the UK. Nursing Times; 104: 3, 44–45.

If you would like to recieve an electronic copy of any of these posters, please inform a Smith & Nephew personnel at our booth - stand number 6.

This poster was presented at EWMA, Brussels 2011
This poster was supported by an unrestricted medical grant from Smith & Nephew.