A liquid film-forming acrylate for peri-wound protection: a systematic review and metaanalysis (3M Cavilon no-sting barrier film)

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CRD summary
This review assessed no-sting barrier film (NSBF) liquid for protecting the skin around chronic wounds (ulcers). The authors concluded that NSBF has a significant protective effect compared with no treatment or a placebo. The strength of the evidence is dubious and anomalies in the analysis cast further doubt on the reliability of the review's findings.

Authors' objectives
To evaluate the effectiveness of no-sting barrier film (NSBF) for the protection of the peri-wound skin of chronic ulcers.

Searching
MEDLINE, EMBASE, CINAHL and the Cochrane Controlled Trials Register were searched; no dates or search terms were reported. Unspecified conference proceedings and wound care journals were searched by hand. Wound care experts were contacted and reference lists in identified papers were checked for additional studies. There was no restriction on language or publication status.

Study selection

Study designs of evaluations included in the review
Randomised controlled trials (RCT) and quasi-randomised trials were eligible for inclusion. RCTs and case-control studies were actually included.

Specific interventions included in the review
Studies of the film-forming liquid acrylate NSBF were eligible for inclusion. The review appeared to focus on Cavilon NSBF manufactured by 3M, but the product used in each of the included studies was not explicit. The included studies compared NSBF with no film, conventional treatment, placebo, zinc paste, zinc oxide or petrolatum. One study compared NSBF with hydrocolloid dressing to hydrocolloid dressing alone. One included study was described as comparing an alcohol-based with a siloxane-based skin protectant. The comparator in one study was not stated.

Participants included in the review
Studies in people with chronic wounds in any care setting were eligible for inclusion. The participants in the included studies were not described.

Outcomes assessed in the review
Studies that reported any objective measure of outcome, such as reduction in erythema or maceration, were eligible for inclusion. Studies that reported only surrogate or objective measures were excluded. The outcomes assessed were grouped under erythema/maceration control, wound healing, cleansing and application time, pain and patient comfort, and ease of application. The actual outcome measures used in each study were not fully defined.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
An instrument developed by the Cochrane Musculoskeletal Injuries Group was modified to assess study quality and assign each study a score out of 30. Two reviewers applied the instrument independently. Any disagreements were resolved by discussion.
Data extraction
Two reviewers independently extracted the data using a standard form. Any disagreements were resolved by discussion. The number of participants or wounds and the number of events in the treatment and control groups in each study were extracted for dichotomous outcomes. Mean and standard deviation values were extracted for continuous outcomes.

Methods of synthesis
How were the studies combined?
A fixed-effect meta-analysis was used to obtain pooled estimates of relative risk or standardised mean difference with 95% confidence intervals for dichotomous and continuous outcomes, respectively.

How were differences between studies investigated?
Studies that compared NSBF with no treatment or placebo and studies comparing NSBF with traditional treatments were pooled separately. The chi-squared test of statistical heterogeneity and the I-squared statistic were integral to the meta-analyses but heterogeneity was not addressed in the review.

Results of the review
Nine studies were included: 7 RCTs (463 participants) and 2 case-control studies (41 participants).

The mean quality score was 20 (range: 14 to 30). The trials were generally of a poor quality and suffered from small sample sizes, short follow-up times, and a lack of data on recurrence rates and the independence of multiple ulcers.

Due to apparent and potentially serious anomalies in the meta-analysis in this review, the pooled results are not reproduced here.

In brief, the meta-analyses showed no significant difference in erythema/maceration control between NSBF and traditional treatments (4 studies) and a significant difference in favour of NSBF compared with no treatment or placebo (4 studies). Cleansing time (2 studies) and application time (1 study) were significantly shorter for NSBF. Pain (2 studies) and patient comfort (1 study) outcomes significantly favoured NSBF.

One RCT (35 patients) showed no difference in wound healing between NSBF and zinc paste.

Authors' conclusions
The main conclusion was that NSBF had a significant protective effect on peri-wound skin compared with no treatment or placebo.

CRD commentary
The review question was not entirely clear about the intervention, the outcomes criterion was imprecise, and the inclusion criteria for study design were not adhered to. The authors did not report taking steps to minimise bias in the selection of studies for inclusion, which is of particular concern because the two authors who conducted the review were employees of the manufacturer of the product on which the review appeared to focus. A number of studies included in the review were also supported by grants from the same manufacturer. Study quality was assessed systematically, but was inadequately reported and not taken into account in the interpretation of the results. It was impossible to judge the potential for bias in the individual studies. There was insufficient information to enable an independent assessment of the clinical similarities and differences between the included studies, or to fully comprehend the study designs. Methods were used to minimise errors in the data extraction, but the actual outcome data extracted from each study for use in the meta-analysis was unclear.

The data appeared to have been pooled in the meta-analysis regardless of study design and without taking account of the unit of randomisation, whether the denominator was patients or wounds, or whether parallel treatment and control groups were compared or patients acted as their own control. Some analyses included more than one set of data from the same study, apparently including the same patients more than once in the same analysis. These anomalies in the
meta-analyses and the lack of information to resolve them cast serious doubt on the reliability of the findings.

**Implications of the review for practice and research**

Practice: The authors stated that NSBF is a safe and effective barrier to protect the peri-wound skin of chronic ulcers. This statement should be interpreted with caution and it should be noted that safety was not assessed in this review.

Research: The authors stated that validated assessment tools for peri-wound skin are needed.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.