Comparing cost per use of 3M Cavilon No Sting Barrier Film with zinc oxide oil in incontinent patients

- **Objective:** This study compares the total cost of treatment, skin-condition management and prevention of skin breakdown of perianal/buttock skin in incontinent patients receiving 3M Cavilon No Sting Barrier Film (Cavilon NSBF) and zinc oxide oil.
- **Method:** This single-centre open-label prospective randomised study involved 40 patients with at least moderate skin damage resulting from incontinence. Patients were randomised to receive either zinc oxide oil or Cavilon NSBF and were treated for 14 days. The study products and other treatment-related products used were recorded, as was the time needed to cleanse the application site and apply the product.
- **Results:** Use of both products resulted in an improvement in skin condition after 14 days, but this was significantly better with Cavilon NSBF than zinc oxide oil. Cavilon NSBF was more cost-effective as fewer applications were required, less time was spent applying the skin barrier product and faster healing rates were achieved. The cost-effectiveness ratio per treatment group showed an improvement of one point in the total score of the skin-assessment scale costs: €28.36 for Cavilon NSBF versus €98.06 for zinc oxide oil.
- **Conclusion:** Both products resulted in an improvement in skin condition after 14 days, but Cavilon NSBF was found to be more cost-effective.
- **Declaration of interest:** This study was supported by an educational grant from 3M.

References

Incontinence is associated with pressure ulcers and skin rashes. Therefore, maintaining healthy, intact perianal/buttock skin is of major importance. Costs associated with incontinence are high and include nursing time and use of absorbent products and skin barrier products, such as petrolatum ointments (Vaseline) and zinc oxide creams and oils. However, petrolatum ointments transfer from the skin to the incontinence pad, interfering with absorption. Zinc oxide creams and oils are messy and need thorough cleansing to remove.

Cavilon No Sting Barrier Film (NSBF) (3M) is an alcohol-free skin barrier delivered in liquid form by a wipe-on applicator (swab) or pump spray. It dries to a flexible, durable and breathable moisture-repellent film on the skin and can be used on reddened or denuded skin. Studies have demonstrated its effectiveness in preventing skin breakdown in incontinent (urine, faeces or both) patients. Cavilon NSBF protects the skin for up to 72 hours, does not interfere with continence-pad absorbency and does not need to be removed before reapplication. This study evaluates the following:
- **Total cost of treatment**
- **Skin condition**
- **Prevention of breakdown of perianal/buttock skin in incontinent patients.**

Method
This single-centre open-label prospective randomised study was approved by the medical ethics committee of the De Heel, Zaans Medical Centre, Zaandam, the Netherlands.

Forty patients with at least moderate skin damage resulting from incontinence were recruited. Skin condition was rated on a non-validated scale from 0 (healthy intact skin) to 12 (severely damaged skin) (Table 1). The nurses were trained how to use the score before the study.

After obtaining consent, patients were randomised to receive either zinc oxide oil or Cavilon NSBF, and treated for 14 days. ClinResearch GmbH, Cologne, Germany, provided the computerised randomisation list and performed the statistical analysis.

Inclusion criteria were:
- Aged 18 years or over
- Incontinence of urine, faeces or both
- Moderate to severe redness in the perianal/buttocks area caused by urine and/or faeces, or moderate to severe erosion of the epidermis in the perianal/buttocks area with mild to moderate involvement of the dermis (very little, if any, exudate) caused by urine and/or faeces, or both
- The patient or his/her representative understood the treatment offered and had received the information sheet
The patient was physically able, in the investigator's opinion, to undergo the test-product treatment and assessment procedures at the frequencies required. The patient or his/her representative had signed the informed consent form.

Exclusion criteria were:
- The patient had other significant skin disease or dermatological problems
- Any medical condition that, in the investigator's opinion, disqualified the patient from participation
- The patient was participating in another study or had participated in one in the previous 30 days.

Treatment regimens
Cavilon NSBF was applied according to the instructions in Table 2. Zinc oxide oil was applied in accordance with the nursing home protocol. Each morning and evening any remaining zinc oxide oil was removed before reapplication. If necessary, it was reapplied at diaper change (all patients wore diapers). Each product application was recorded in a material list. Patients were given their own container of zinc oxide oil or a spray-bottle of Cavilon NSBF. Before and after the first two applications, a digital balance was used to weigh the amount needed for these and subsequent applications.

After skin-condition assessment, the perianal/buttock skin was washed. The time taken to do this was recorded for the first two applications only. Each incontinence pad and diaper change was also recorded in the material list, along with the type of incontinence (urine or faeces or both).

Skin assessment was repeated daily by completing the skin condition assessment form (Table 1). Photographs were taken on days 0, 1, 2 and 7, and at the end of the treatment period (on healing or at day 14). Healing was determined when the skin score was 0.

Statistical analysis

Statistical basis of sample size
Based on pilot data, a conservative estimate of the difference in total cost per day of treatment was approximately €4, with an estimated standard deviation of 2.0. A sample of only three subjects per group is needed to detect such a difference in cost. As an alternative, the study sample size was based on the comparison of efficacy (skin condition) between the groups. A previous study provided an estimate of the standard deviation of 2.1 for the total skin-condition score. To detect a difference from baseline, with a two-tailed alpha of 0.05 and a power of 80%, a sample of 19 patients per group is needed.

Data management
Data were analysed using SAS, version 8.2. The change in skin condition from baseline in the Cavilon NSBF group was compared with that in the zinc oxide oil group at day 14 only (or the last day in the study), using a two-sided t-test (p=0.05).

The main objective was to detect a significant difference in the total cost of using the study products over a 14-day period. These comprised the:
- Cost of the study products used
- Cost of additional treatment-related products (excluding diapers)
- Cost of the time spent removing the study product, washing the perianal/buttock area, and the time spent applying the study product when a diaper was changed
- Cost of the time spent changing the diaper and washing the perianal/buttocks area without applying the study product.

The total cost of the study products, other treatment-related products and nursing time were averaged within each treatment group and compared using a two-sided t-test. Where patients finished the study early, the costs were calculated using the mean costs per documented day.

A cost-effectiveness ratio was calculated by dividing the difference in mean total cost between the groups by the difference in mean change in patient skin condition from baseline on a 12-point scale.

Table 1. Skin condition assessment scale

<table>
<thead>
<tr>
<th>Redness of the skin (area)</th>
<th>Redness of the skin (severity)</th>
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<tbody>
<tr>
<td>0 No redness</td>
<td>0 No redness</td>
</tr>
<tr>
<td>1 Small area (&lt;20cm²)</td>
<td>1 Mild redness</td>
</tr>
<tr>
<td>2 Moderate area (20–50cm²)</td>
<td>2 Moderate redness</td>
</tr>
<tr>
<td>3 Large area (&gt;20cm²)</td>
<td>3 Serious redness</td>
</tr>
</tbody>
</table>

Table 2. Cavilon NSBF application instructions

<table>
<thead>
<tr>
<th>Skin score</th>
<th>No. of diaper changes per day</th>
<th>Application frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–5</td>
<td>1–3 per day</td>
<td>Every 72 hours</td>
</tr>
<tr>
<td>&gt;3 per day</td>
<td>Every 48 hours</td>
<td></td>
</tr>
<tr>
<td>6–12</td>
<td>1–3 per day</td>
<td>Every 48 hours</td>
</tr>
<tr>
<td>&gt;3 per day</td>
<td>Every 24 hours</td>
<td></td>
</tr>
</tbody>
</table>

9 Hughes, S. Do continence aids help to maintain skin integrity? J Wound Care 2002; 11: 6, 235-239.
Results
Data from 39 of 40 randomised patients were available for the final analysis. Ten patients terminated the study prematurely for the following non-study-related reasons: healing (n=5), death (n=4), high fever and hypotension (n=1). Costs relating to these 10 patients were calculated using the mean costs per documented day.

Demographic and baseline characteristics
Most of the patients (66.7%) were female: 73.7% in the Cavilon NSBF group and 60% in the zinc oxide oil group. Mean patient age was 85.1 ±7.2 years and 83.3 ±7.8 years and body mass index (BMI) was 24.9 ±6.1 and 22.9 ±3.4 respectively. BMI was measured as patients with a high BMI might have been more susceptible to skin breakdown. There were no significant differences between the two patient populations, or in concurrent diseases.

Skin-condition assessment
Total scores at day 1 and at the last observation were assessed. Total skin damage scores improved with both treatments, but were significantly better with Cavilon NSBF (p=0.04). While the area of redness improved slightly more when compared with zinc oxide oil, severity of redness was distinctly reduced (47.4% and 15%) in the test group. Similar results were seen for area and severity of skin denudation: 42.9% versus 16.7% and 35.7% versus 8.3%.

Cost analysis
- **Product cost** - The cost of the study products and the application-related products (such as gloves, spatula, gauze) was £7.55 ±8.60 for the test group and £14.16 ±1.83 for the zinc oxide oil group.
- **Nursing time** - Total nursing time (such as removal, cleansing, application) incurred during the study period and related costs were analysed. The mean total nursing time for the Cavilon group was 161.96 minutes (SD 55.55) and for the zinc oxide oil group 208.95 minutes (SD 53.84). The mean cost of the total nursing time was higher in the zinc oxide oil group (£88.20, SD22.88) than in the Cavilon NSBF group (£68.58, SD23.61). The cost of nursing time was calculated as £25.50/hour.
- **Total cost** - The total cost per treatment group was calculated as the sum of the study costs plus the costs of treatment-related products such as non-sterile gloves, spatula, gauze, sweet oil and disposable bowls as well as the nursing costs. The mean total costs were higher in the zinc oxide oil group (£102.96, SD 23.25) than in the Cavilon NSBF group (£76.13, SD 25.48).
- **Cost-effectiveness ratio** - This ratio was calculated by dividing the difference in mean total costs between the zinc oxide oil and Cavilon NSBF group by the difference in the mean change in the patient's skin condition from baseline on the 12-point scale. An improvement of one point in the total score of the skin-assessment scale cost £28.36 for Cavilon NSBF and £98.06 for zinc oxide oil.

Discussion
Incontinence dermatitis and further skin breakdown not only have a significant impact on patients and carers, but also the cost of care increases significantly due to the additional time and supplies required.

It is therefore interesting to note that, in their literature review, Scardillo and Anonovitch concluded that irritant dermatitis from body fluids is either not an issue in health care or that only a few individuals have recognised it as a health-care concern.

This lack of supporting clinical evidence presents difficulties for caregivers in prescribing the most effective treatment. Most studies conclude that more research is needed to determine the effectiveness of protocols used to treat and prevent incontinence dermatitis. Hunter et al. stated that a plethora of skin-care products are available and selection is, at times, based on cost, convenience and marketing strategies, rather than scientific evidence.

In 1992 Lyder et al. concluded that research is needed to validate the efficacy of a structured skin-care regimen to prevent perineal dermatitis.

More recently, Hughes' literature review of the efficacy of continence aids such as pads and barrier creams and their role in maintaining skin integrity concluded that many studies had flaws and new research is needed to avoid subjective selection.

When introduced to Cavilon NSBF, we reviewed the available clinical research data and came to a similar conclusion. A few studies were available but mainly reported individual cases. Although statements were found on cost-effectiveness, no supportive research data were identified.

Based on the ease of use and good results reported for Cavilon NSBF in incontinent care, we decided to perform a controlled randomised cost minimisation study. At the beginning of this study we had 259 occupied beds in our nursing home. The point prevalence of incontinence was 64.9%.

The results led to a change in protocol, and might lead to a significant cost reduction in a larger nursing home in the Netherlands. The product's characteristics made it impossible to conduct a blinded study.

Conclusion
This study has shown that zinc oxide oil or Cavilon NSBF helped improve the patients' skin condition. Efficiency data revealed that Cavilon NSBF is significantly more cost-effective than zinc oxide oil because of the lower product application frequency, with savings in limited and expensive nursing time. An additional benefit is the ensuing reduction in patient discomfort and suffering.