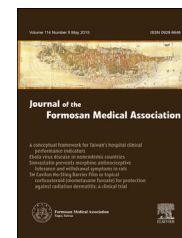


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## ORIGINAL ARTICLE

# 3M Cavilon No-Sting Barrier Film or topical corticosteroid (mometasone furoate) for protection against radiation dermatitis: A clinical trial



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**KEYWORDS**

barrier;  
corticosteroid;  
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dermatitis;  
skin

**Background/Purpose:** Evidence on the prevention of radiation dermatitis is lacking. The aim of this study was to investigate the effect of 3M Cavilon No Sting Barrier Film and topical corticosteroids on irradiated skin.

**Methods:** Thirty-nine postoperative breast cancer patients were randomized into three groups for intraindividual comparison (skin to be irradiated was divided into 2 parts): (1) 3M No Sting Barrier Film versus no treatment; (2) corticosteroid versus no treatment; and (3) corticosteroid versus 3M No Sting Barrier Film. The primary end points monitored were the time to first occurrence of grade 1 pruritus, pain score of 3 and grade 2 radiation dermatitis. The secondary end points studied were the incidence of grade 3 radiation dermatitis and total pain scores. Data analysis was done using the SPSS software version 10.

**Results:** Skin given the 3M barrier film experienced a later occurrence of pruritus compared to both corticosteroids and untreated, although this was statistically insignificant. Corticosteroids delayed the time to occurrence of grade 2 dermatitis compared to both untreated skin and 3M barrier film, (mean day of onset = corticosteroid: 52 vs. untreated: 43,  $p = 0.092$ ; corticosteroid: 53.4 vs. 3M barrier film: 44.5,  $p = 0.002$ ,  $t$  test). Skin given corticosteroids had the lowest incidence of grade 3 dermatitis among all three conditions, although the differences were statistically insignificant. No statistically significant differences were noted in total pain scores.

Conflicts of interest: The authors have no conflicts of interest relevant to this article.

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**Conclusion:** The 3M barrier film may be helpful against dermatitis associated pruritus. Corticosteroids may delay the time of onset of severe skin reactions and also reduce the incidence of severe radiation dermatitis.

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## Introduction

The human epidermis is a relatively radiosensitive organ; it goes through a series of physical changes as the radiation dose accumulates over time. A skin reaction is commonly observed when treatment is delivered to the head and neck region, breast, post-modified radical mastectomy chest wall, axilla, groin area or the perineum. These physical reactions caused by radiation may result in much discomfort that affects the general well being of a patient. If severe, the treatment course may even be interrupted.

Several studies have been conducted to find ways of preventing and managing radiation skin reactions. Products, either medicated or non-medicated, in the form of lotion, cream, ointment, barrier film or dressing etc, were used in the trials; however, there was lack of strong evidence and consensus on the issue regarding what to use for radiation protection and management. One particular reason was that, as pointed out by Maurene McQuestion and other reviewers, it is difficult to make comparisons across studies due to methodological weaknesses, such as small sample sizes, a wide variety of terms describing reactions, a variety of measuring tools and different outcomes across studies.<sup>1,2</sup> Furthermore, according to Kumar's review, only seven out of 29 articles (studies from 1980 to 2008) demonstrated statistically significant results for the management of acute skin toxicity.<sup>3</sup> The Cancer Care Ontario's Supportive Care Guideline Group, the Belgium nursing group and researchers such as Kumar in Australia, and Lavery in the UK, all agreed and recommended gentle skin washing using either water alone, or with mild soap, for the prevention of radiation skin reactions. However, they also concluded that there is insufficient evidence to support or refute specific oral or topical agents for the prevention and management of radiation dermatitis, because there were too many inconsistencies among the trial results.<sup>4-6</sup>

Breast cancer patients constitute the majority treated in our radiation department. During the course of radiotherapy, many patients suffered from dermatitis > grade 2 according to the NCI Common Terminology Criteria for Adverse Events version 3.0 (Table 1). When moist desquamation occurred, patients often experiences pain and burns that may last for weeks after treatment. Some skin breakdown was accompanied by exudates and crusting, requiring dressing, medication and special wound care, and this usually caused anxiety, limited activity and inconvenience in clothing other than pain and discomfort. This urged us to find some evidence for protection against radiation-induced irritation and dermatitis. We think it is equally as important to minimize the patient's suffering during radiation treatment, as to achieve cancer control.

This study thus focused on breast cancer patients, comparing two products and untreated skin. These products contain two distinctive properties: (1) Mometasone

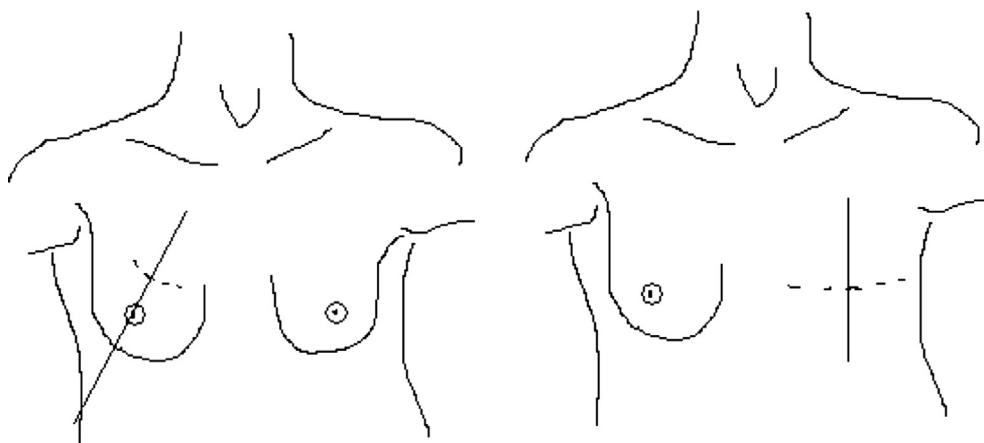
furoate cream containing 0.1% topical corticosteroid (Elo-met), which contains chemical antiinflammatory effects; and (2) 3M Cavilon No-Sting Barrier Film, which is a non-medicated product that acts as a physical barrier on the skin against friction and contamination. Elomet was routinely used in our department once a patient experienced skin itches and pain, but was not advised in the area of epidermal breakdown or wet desquamation, due to its adverse effects on wound healing.<sup>7</sup> Bostrom et al reported that the use of mometasone furoate reduces the incidence of grade IV skin reactions when compared to an emollient (35% vs. 60%).<sup>8</sup> 3M Cavilon No-Sting Barrier Film was introduced to our department later. The Australian group, Graham et al, used 3M Cavilon No-Sting Barrier Film and found that it reduces the duration and frequency of radiation-induced moist desquamation and the pruritus score as compared to sorbolene cream.<sup>9</sup>

## Materials and methods

The IRB committee in our hospital approved this clinical study, and a total of 39 patients were recruited from November 2008 to December 2010. All participants signed inform consent to this study. Each patient was allocated to one of the three treatment combinations by simple randomization: (1) 3M barrier film versus no treatment; (2) Elomet versus no treatment; and (3) Elomet versus 3M barrier film. Then, each patient's chest wall, or remaining breast after breast conserving surgery, was divided into two skin regions perpendicular to the scar (Fig. 1). On either side, we applied 3M barrier film, Elomet or left it as untreated; therefore, each patient had two skin regions used

**Table 1** Common Terminology Criteria for Adverse Events v3.0 (CTCAE).

Grade	Criteria
<i>Dermatitis associated with radiation</i>	
1	Faint erythema or dry desquamation
2	Moderate to brisk erythema; a patchy moist desquamation, mostly confined to skin folds and creases; moderate edema
3	Moist desquamation other than skin folds and creases; bleeding induced by minor trauma or abrasion
4	Skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site
5	Death
<i>Pruritus/itching</i>	
1	Mild or localized
2	Intense or widespread
3	Intense or widespread and interfering with ADL



**Figure 1** Each patient's chest wall or remaining breast after breast conserving surgery is divided into two skin regions perpendicular to the scar for different applications.

for intraindividual comparison. Each division might have included axilla, breast–sternum junction and lower breast skin fold in patients receiving breast conserving surgery. The purpose of this internal control method was intended to exclude variables, such as previous chemotherapy, individual sensitivity, or co-morbidities.

Standard radiation fractionation (2 Gy per fraction, five fractions per week) was used in each patient. Each patient underwent computed tomography for treatment planning. A total of 50 Gy was delivered using tangential field to the remaining breast or chest wall. Wedge filters, bolus and subfields were applied when necessary, to obtain a uniform dose distribution. Then, a dose of 10 Gy boost to the tumor bed and scar region was delivered using electrons. For patients with more advanced disease, such as lymph node involvement or chest wall recurrence, regional lymph nodes (axillary, supraclavicle and internal mammary chain) were also irradiated. The skin reaction in the supraclavicular or neck region was not taken into account in this study.

Both Elomet and 3M barrier film were applied to the allocated skin region every other day, excluding weekends, during the radiation treatment period, mostly by the same hospital staff. Skin reactions on the breast or chest wall were observed, and photographed. Patient assessed itching and pain scores were recorded weekly, from the beginning of irradiation, until 4 weeks after completion of treatment by the same staff. The severity of dermatitis and pruritus was graded according to NCI Common Terminology Criteria for Adverse Events version 3.0 (Table 1). Pain score was graded on a scale of 1 to 10. The day of onset of each event was given a date from the first day of radiation treatment for each category. If generalized wet desquamation occurred, the application of both products was stopped. Ointment containing an antibiotic was prescribed during the irradiation, or silver sulfadiazine cream was prescribed if radiation treatment was completed.

The primary end points monitored were the time to first occurrence of grade 1 pruritus, a pain score of 3 and grade 2 dermatitis. The secondary end points were the incidences of grade 3 acute dermatitis and total pain scores recorded in each different application (Elomet (mometasone furoate cream), Schering-Plough; East- Java, Indonesia, 3M barrier film (3M no-

sting Cavilon Barrier Film, 3M Health Care; Minnesota, USA) or untreated). Data analysis was done using the SPSS software version 10. Pair *t* test was performed to compare the times to first occurrence of Grade 1 pruritus, pain score of 3 and Grade 2 dermatitis between any two applications in all three groups. For the incidences of Grade 3 dermatitis which occurred in each skin condition, a Chi-square test was performed to compare the differences. As for total pain score comparison, we took the sum of the pain scores recorded each week for each patient from week 1 to 10 and tested the differences using Wilcoxon signed-rank test. In statistical testing, a two-sided *p* value  $\leq 0.05$  was considered statistically significant.

## Results

Thirty-nine patients entered the study; 13 patients were in the 3M barrier film versus no treatment group, nine were in the Elomet versus no treatment group, and 17 were in Elomet versus 3M barrier film. These patients ranged from 30 to 76 years old; mean age = 51 years. There were 17 patients who had previously received modified radical mastectomy, 18 had received breast conservation treatment, and four had post-modified radical mastectomy chest wall recurrence and received tumor excision.

In the group using 3M barrier film and Elomet application, we found that skin using 3M barrier film experienced a later occurrence of Grade 1 pruritus than the use of Elomet (3M: day 32.4 from first treatment day vs. Elomet: day 28.4). However, this was not statistically significant;  $p = 0.072$ . In the 3M barrier film versus the untreated group, it appeared that the application of 3M barrier film may also delay the occurrence of pruritus in patients (3M: day 32.5 vs. untreated: day 29.4), but again, the *p* value was insignificant;  $p = 0.079$ . In the Elomet versus the untreated group, no difference was shown (Elomet: day 26.4 vs. untreated: day 26.8,  $p = 0.413$ ). Fig. 2 shows the mean pruritus score in each application by week of radiotherapy.

Comparing the differences of time to first occurrence of pain score of 3 in all three groups, we found no significance differences in all three applications ( $p = 0.451$  comparing 3M barrier film and Elomet,  $p = 0.527$  comparing Elomet

with untreated, and  $p = 0.618$  comparing 3M barrier film with untreated).

Looking at the time to first occurrence of grade 2 dermatitis, the group Elomet versus 3M barrier film, showed that by applying Elomet, dermatitis occurred later than the use of 3M barrier film (Elomet: day 53.4 vs. 3M barrier film: day 44.5). This difference reached statistical significance;  $p = 0.002$ . In the group of Elomet versus the untreated group, Elomet also appeared to delay the time onset of Grade 2 dermatitis compared to untreated skin, but it showed no statistical significance;  $p = 0.092$  (Elomet: day 52 vs. untreated: day 43). Figs. 3 and 4 show skin reactions of unequal severity in these two groups. In the 3M barrier film group versus the untreated group, there were similar results between the two (3M barrier film: day 44.2 vs. untreated: day 46.6,  $p = 0.196$ ). The summary and comparison regarding the time to first occurrence of these adverse events is shown in Table 2.

No Grade 4 acute radiation dermatitis was observed in any of the three different applications. The overall incidences of acute skin reaction of Grade 3 dermatitis irrespective of grouping were: (1) 3M barrier film: 10 out of 30 (33%); (2) Elomet: four out of 26 (15%); and (3) untreated: five out of 22 (23%). However, using the Chi-square test to compare these results showed that it was statistically insignificant;  $p = 0.289$ . As for the total pain score recorded with application of 3M barrier film, Elomet and untreated skin, no statistically significant difference was reached in any group using the Wilcoxon sign-rank test. By comparing 3M barrier film with no treatment, the  $p$  value was 0.759. By comparing Elomet with no treatment, the  $p$  value was 0.786. By comparing Elomet with 3M barrier film, the  $p$  value was 0.369.

## Discussion

Radiation induced skin reactions is a continuous process; as the radiation dose accumulates, the severity increases. It

involves (1) disruption of the balance between the normal production of cells at the basal layer and the destruction or death of cells at the skin surface; (2) a cascading inflammatory response triggered by injured cells, with release of histamines, serotonin and other proinflammatory molecules; and (3) vascular response.<sup>1,10</sup> It has been documented that 87% of people suffer a moderate to severe reaction.<sup>11</sup> Generally, erythema may occur after 2–3 weeks of radiation, as a result of capillary dilatation in the dermis accompanied by edema, because of increased vascularity and obstruction.<sup>12,13</sup> As the accumulative dose reaches 20 Gy, decreased ability of the basal layer cells to replace surface layers and decreased functioning of the sweat gland and sebaceous gland, result in dryness, pruritus, or flaking of the skin, also known as dry desquamation.<sup>14</sup> At a dose of 30–40 Gy, extracapillary cell damage occurs with increased capillary blood, so we observe hyperemia and edema. Moist desquamation may occur at doses of 45–60 Gy where the dermis is exposed. The treatment field is moist, tender and red, with oozing of serous fluid, or it may be accompanied by exudates and crusting.<sup>12</sup> Ulcer formation, hemorrhage, and necrosis are less common but represent more severe damage.<sup>1,15</sup> These skin changes are identified and graded by severity (Table 1).

Factors affecting the severity of skin reaction include both patient-related factors and treatment-related factors. Patient-related risk factors include: concurrent chemotherapy, immunotherapy, or target therapy, associated medical condition or co-morbidities such as diabetes or renal failure, old age, compromised nutritional status, smoking chronic sun exposure, and other environmental conditions.<sup>16,17</sup> Treatment-related risk factors include location of treatment field (e.g., chest wall, head and neck, facial, skin folds, breast, axilla, perineum), a larger treatment volume, larger fraction dose (>2.0 Gy per fraction), larger total dose, lower energy photon or electron used, and the use of bolus material.<sup>16–18</sup> Skin areas where two skin surfaces are in contact (e.g., breast inferior portion, perineum), where the epidermis is thin and smooth

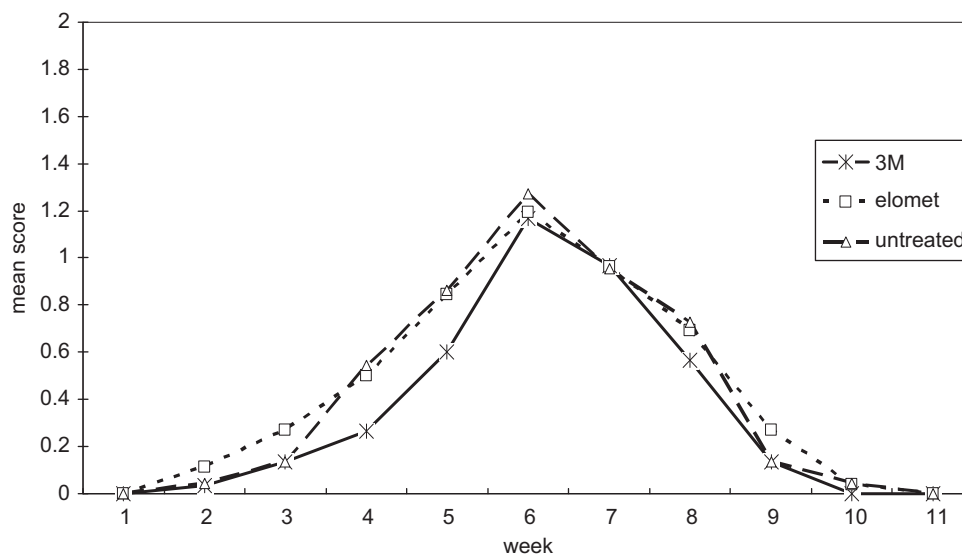


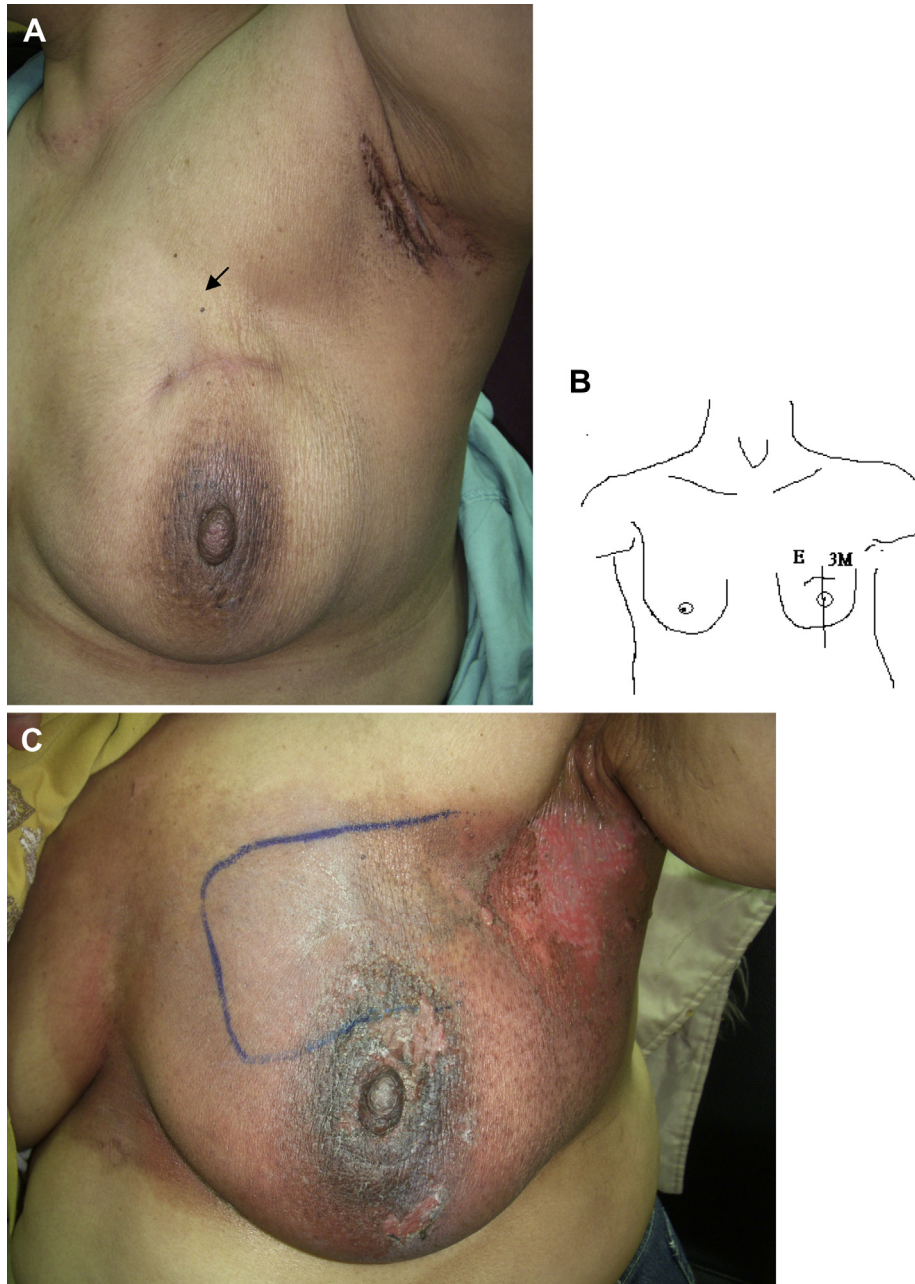
Figure 2 Weekly mean patient-assessed itchy scores by each application.

(e.g., axilla, face, perineum), or where skin integrity has been disrupted (e.g., surgical wound, lesions, burn) are at greater risk for a more severe reaction.<sup>16</sup>

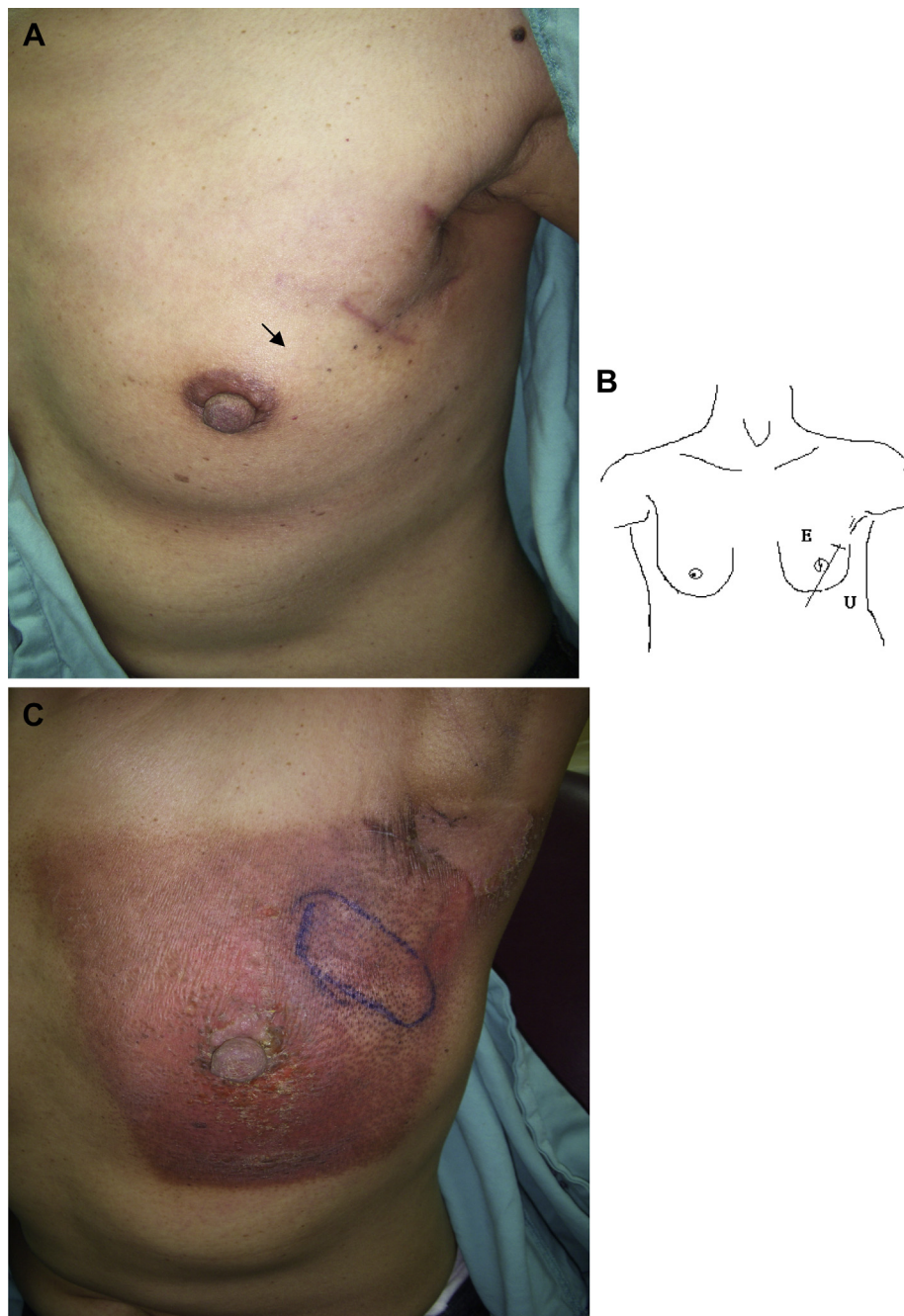
In our study, we had taken into consideration that symptoms assessed might be subjected to individual sensitivity and tolerance, such as itch and pain, and that numerous patient-related risk factors mentioned above would greatly affect the outcome, if each application was tested on different individuals, as done in many other trials; henceforth, we used intraindividual comparisons (each patient was given 2 different applications). The shortcoming of our study, however, was the small sample size in

each group that might affect the significance of the outcomes.

Two outcomes caught our attention. Firstly, 3M barrier film may be helpful against radiation induced pruritus. It was shown in both groups (3M barrier film vs. Elomet and 3M barrier film vs. untreated) that the skin using 3M barrier film delayed the appearance of pruritus as compared with Elomet and untreated skin. Secondly, corticosteroid may delay the time to occurrence of grade 2 dermatitis compared with both untreated skin and 3M barrier film. The difference reached statistical significance when Elomet was compared with 3M barrier film.



**Figure 3** Photo of skin reaction on the 46<sup>th</sup> day (C); Elomet vs. 3M barrier film where Elomet (E) is applied on left side of photo and 3M barrier film (3M) on right side, as shown in diagram on the right (B); the arrow points to the dotted line of division on day 0 (A). Reaction is more severe on the 3M barrier film side (C).



**Figure 4** Photo of skin reaction on the 50<sup>th</sup> day (C); Elomet vs. untreated where Elomet (E) is applied on left upper of photo and untreated (U) on right lower as shown in diagram on the right (B); the arrow points to the line of division on day 0 (A). Reaction is more severe on the untreated side (C).

It has been documented that 3M Cavilon No Sting Barrier Film can be used in many clinical situations, including stoma care, protection of skin against body wastes such as in incontinence, peri-wound protection from exudates irritation, and protection under adhesive dressing and tapes.<sup>19</sup> Upon application, it forms a long lasting waterproof barrier on the damaged skin. It acts as a protective interface between the skin and wound fluids, body wastes, perspiration, adhesive products and friction.<sup>20</sup>

We hypothesized that, by preventing further water loss from the skin surface and forming a protection against

further irritation, 3M barrier film was able to reduce itching and delay the occurrence of itching. Our study was consistent with that of Graham and Schuren. They also found that with use of 3M barrier film, patients benefited in terms of reduced pruritus score and increased patient comfort.<sup>9,20</sup>

Many studies have confirmed the potent antiinflammatory effects of topical corticosteroid. Corticosteroid exerts anti-inflammatory effects through many pathways, including the inhibition of the release of the enzyme, phospholipase A2, inhibition of proinflammatory gene transcription factors,

**Table 2** Summary and comparison regarding the time to first occurrence of adverse events.

Events	Group		
	3M vs. untreated	Elomet vs. untreated	Elomet vs. 3M
Time to gr. 1 pruritus	D 32.5 vs. D 29.4 $p = 0.079$	D 26.4 vs. D 26.8 $p = 0.413$	D 28.4 vs. D 32.4 $p = 0.072$
Time to pain score 3	D 38.5 vs. D 37.5 $p = 0.618$	D 41.5 vs. D 41.2 $p = 0.527$	D 45.2 vs. D 45.7 $p = 0.451$
Time to gr. 2 dermatitis	D 44.2 vs. D 46.6 $p = 0.196$	D 52 vs. D 43 $p = 0.092$	D 53.4 vs. D 44.5 $p = 0.002 (p < 0.05)$

inhibition of phagocytosis and decrease of the release of proinflammatory cytokines such as IL-1 and IL-6.<sup>21,22</sup> Corticosteroid also induces vasoconstriction, decreases capillary permeability, and inhibits leukocyte proliferation and migration.<sup>23</sup> Janko et al found that mice lacking either IL-1 or IL-1 receptors, developed less inflammation and less severe pathological changes in their skins, especially at the later time points when these mice were put under irradiation,<sup>10</sup> linking the IL-1 pathway directly to radiation dermatitis. Furthermore, Beetz et al reported that corticosteroids can inhibit the upregulation of IL-6 expression in an irradiated human epithelial cell line.<sup>24</sup> Elomet (mometasone furoate), the corticosteroid cream, has three properties. Firstly, it is a potent corticosteroid with a low risk of cutaneous atrophy, secondly, it has a prolonged effect lasting 24 hours, that is convenient to apply,<sup>8</sup> and thirdly, it has been confirmed that mometasone furoate has an inhibitory effect on IL-6 activity in the lab.<sup>24</sup> Our finding was concordant with these studies, since Elomet in our study was shown to delay the time onset of Grade 2 dermatitis by exerting its anti-inflammatory effect.

Although the incidence of grade 3 dermatitis in the Elomet application was not statistically superior to the other two, we found it is the lowest among the three applications, 15% against 23% and 33%. This result again was consistent with Elomet, the corticosteroid, having the anti-inflammatory effect, and may be helpful in reducing radiation dermatitis; however, it was most likely due to our small sample size that this result could not reach statistical significance.

In theory, if Elomet is able to reduce the severity of dermatitis, it should also have an effect on pain and itch symptoms, but our study did not clearly show this, while other published studies showed significant findings of mometasone furoate against pain, itching or other irritations, compared to placebo.<sup>8,25,26</sup> Bearing in mind that these studies test their materials on two different groups of individuals, our tentative explanations are that since we put Elomet and untreated in the same large skin area on the same individual, perhaps it was difficult to distinguish which side was less irritated, when the symptom is subtle and obscure, and perhaps the symptoms may refer to the other side by nerve pathways.

## Conclusion

It seems that, with prolonged exposure to radiation, dermatitis of some degree would eventually occur in time

as a natural process, irrespective of any product used. Gentle washing with or without pH balanced soap should be encouraged during the course of treatment. According to our study results and observations, we also recommend 3M barrier film to reduce friction and irritation, particularly at the skin folds and in thin skin areas, such as axilla. It may be applied from the beginning of radiotherapy. Once the hyperemia and pain appear, topical corticosteroid is suggested to reduce inflammation and 3M barrier film may be discontinued. The effectiveness of corticosteroid on prevention of radiation dermatitis should be further investigated under a larger randomized trial.

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