StrataXRT®
for the management of radiation induced skin reactions
Radiation Dermatitis – The Unwelcome Consequence of a Life-Saving Therapy

Radiation dermatitis is an acute skin reaction affecting approximately 95% of patients who receive radiation therapy to the breast, groins or perineum. It generally ranges from erythema to dry or even moist desquamation and can be a source of significant pain, discomfort and psychological distress. In particular, moist desquamation poses the risk of infection and can result in treatment breaks which impair patient outcomes.

- Up to 50–60% of patients receiving cancer treatment will undergo radiation therapy at some stage of their illness.
- The introduction of modern mega-voltage treatment machines with skin-sparing capabilities have improved but not eliminated skin toxicities.

How do the current therapies rate?

Studies assessing lotions, creams, or emulsions (aloe vera, hyaluronic acid, corticosteroids, sucralfate) either showed no benefit in managing radiation dermatitis or provided conflicting evidence.

It is essential that any skin damage is minimized by ensuring that interventions are based upon best practice, and supported by evidence-based guidelines.

The introduction of modern mega-voltage treatment machines with skin-sparing capabilities have improved but not eliminated skin toxicities.

Consensus goals of care for skin reactions during radiation therapy

<table>
<thead>
<tr>
<th>StrataXRT scores</th>
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</thead>
<tbody>
<tr>
<td>Initial maintenance of skin integrity</td>
</tr>
<tr>
<td>Reduced potential of further exacerbation of skin reactions</td>
</tr>
<tr>
<td>Minimized water loss and optimized skin hydration by means of topical agents</td>
</tr>
<tr>
<td>Promotion of comfort and compliance</td>
</tr>
<tr>
<td>Reduction of pain and pruritus without causing a bolus effect</td>
</tr>
<tr>
<td>Control of bleeding, odor and excessive exudate</td>
</tr>
<tr>
<td>Provides ideal environment for rapid healing and re-epithelialization</td>
</tr>
<tr>
<td>Promotion of moist wound healing environment where skin is broken</td>
</tr>
<tr>
<td>Protection from trauma &amp; friction</td>
</tr>
<tr>
<td>Protection of infection</td>
</tr>
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</table>
The RTOG Scale for Radiation Dermatitis

The RTOG scale (Radiation Therapy Oncology Group) provides a standardized description of radiation induced side effects. Interventions are usually matched to the skin’s reaction based on its assessment and the RTOG score.

<table>
<thead>
<tr>
<th>RTOG Scale Score</th>
<th>Observation: External Signs</th>
<th>Observation: Cellular Level</th>
<th>Clinical Assessment</th>
<th>Treatment Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No visible change to skin</td>
<td></td>
<td></td>
<td>Maintain soft, supple, clean, odor free and intact skin.</td>
</tr>
<tr>
<td>1</td>
<td>Redness. Inflammation</td>
<td>Mild tightness/itch</td>
<td></td>
<td>Maintain soft, supple, clean odor free, intact skin, reduce irritation and promote comfort.</td>
</tr>
<tr>
<td>2</td>
<td>Sensitive skin with bright redness With/without dry desquamation</td>
<td>Tightness/itch/sore</td>
<td></td>
<td>Promote skin hydration, comfort and maintain skin integrity. Reduce itch, pain, soreness and discomfort.</td>
</tr>
<tr>
<td>2.5</td>
<td>Patchy moist desquamation</td>
<td>Moderate oozing</td>
<td></td>
<td>Reduce risk of complications of further trauma and infection. Reduce pain, soreness and discomfort.</td>
</tr>
<tr>
<td>3</td>
<td>Confluent moist desquamation Pitting oozing</td>
<td></td>
<td></td>
<td>Reduce the risk of infection, minimize pain and trauma of the skin.</td>
</tr>
<tr>
<td>4</td>
<td>Ulceration, bleeding, necrosis</td>
<td></td>
<td></td>
<td>Debride the wound. Control associated bleeding and oozing (exudate), minimize effects of wound infection.</td>
</tr>
</tbody>
</table>

Photos from several patients. Other scales of measurement include RISRAS and CTCAE. The key measurement point on this RTOG scale is level 2.5 (2b), which denotes the first level of the appearance of moist desquamation.

Images (RTOG 0–3) courtesy of The Princess Royal Radiotherapy Review Team, St James’s Institute of Oncology, The Leeds Teaching Hospitals NHS Trust. Taken from the publication “Managing Radiotherapy Induced Skin Reactions, a Toolkit for Healthcare Professionals”.

Progression of symptoms and skin changes according to the RTOG scale during radiation therapy*

![Progression of symptoms and skin changes](image)

* Curve generated from the general progression of radiation dermatitis for patients undergoing radiation therapy. Levels of reaction differ significantly between patients and treatments. If untreated however the level of reaction generally follow the shape of this curve.
Why is StrataXRT an Innovative Wound Dressing?

StrataXRT film-forming gel dries as a thin, flexible and protective layer that is gas permeable, waterproof, inert and has no measurable pH value.

- Can be applied from day one of radiation therapy
- Faster re-epithelialization promoted by a moist wound healing environment
- Does not cause bolus effect
- Lightly bonds to the most superficial damaged layer of the skin
- Sterile, biologically inert and bacteriostatic
- Fast drying
- For best result, leave in constant contact with the skin
- Full contact flexible wound dressing

Management of Radiation Dermatitis with StrataXRT

StrataXRT helps to reduce Trans Epidermal Water Loss (TEWL) while promoting a moist wound healing environment, leading to:

- Faster re-epithelialization of the skin post-therapy
- Relief of low grade cutaneous changes such as dry, itching, flaking, peeling and irritated skin
- Reduced pain, redness and heat, while helping to soothe exposed areas in more severe inflammatory changes

StrataXRT protects the fragile epidermis during dry desquamation leading to:

- Preservation of the skin integrity
- Prevention of excessive sloughing of the outmost layers

StrataXRT protects the dermal stroma from long-term deterioration during moist desquamation leading to:

- Optimization of the environment for the reparative process
- Reducing the risk of infection
Clinical Study

A 28-patient multicenter study performed in Spain (2015). Starting of therapy: RTOG score of 2.5 ± 0.5. All patients were treated with StrataXRT while undergoing radiation therapy. StrataXRT reduces the severity of radiation induced skin reactions and significantly decreases the RISRAS score, even if patients are undergoing radiation therapy treatment.

During the application period, StrataXRT showed a decrease of pain by 20.48%*, of the itching by 22.22%*, of the burning sensation by 24.69%*, the erythema by 21.13%* and an improvement of the hydration by 26%*. (*p-value <0.05)

StrataXRT Does Not Cause Bolus Effect

The Springfield Radiation Oncology Center in Australia conducted measurements on increasing electron beam energy levels to verify the bolus effect of a clinical dose of StrataXRT. This study showed that StrataXRT does not cause a bolus effect since the energy of the beam is not affected by the product.

Method
Figure 1 shows the experimental setup of the dosimetric measurement. Three readings were made for each of the energy levels (6, 9, 12, 16 MeV). The first time without the application of StrataXRT, the second time with the application of StrataXRT.

Measurements at Different Energy Levels with and without StrataXRT Application

Figure 1
Radiation Dermatitis Case Studies: All patients continued radiation therapy while applying StrataXRT

Case Study Korea, 2015
Yonsei University Health System, Severance Hospital, Korea

A series of case studies was performed for treatment of radiation dermatitis at different RTOG stages of toxicity. Patients and nurses reported an overall improvement, reduced itching and pain symptoms. Patients positively evaluated the transparency of StrataXRT once it dried, while protecting the affected area.\textsuperscript{15}

Head and Neck Cancer

Patient showing a RTOG 3 radiation dermatitis with moderate edema and a confluent moist desquamation.

Patient applied StrataXRT during ongoing radiation therapy. After 7 days of topical treatment, the moist desquamation and edema resolved and the skin pigmentation improved.

Patient showing a severe RTOG 2.5 radiation dermatitis with a marked edema with superficial ulceration and a confluent moist desquamation.

Patient applied StrataXRT during ongoing radiation therapy. After 3 days of topical treatment there is no longer a sign of patchy moist desquamation. Patient shows a decrease of the edema but still a persisting depigmentation of the skin.
Radiation Dermatitis Case Studies: All patients continued radiation therapy while applying StrataXRT

Case Study Spain, 2015
Hospital Universitario de Fuenlabrada, Hospital Ruber Internacional, Madrid Spain

A series of case studies was performed on patients with a RTOG score of 2.5 ± 0.5. Patients and nurses reported an overall improvement, reduced itching and pain symptoms. Patients appreciated the ease of use as well as the comfort provided by StrataXRT.

Head and neck cancer

Patient showing a RTOG 3 radiation dermatitis with moderate edema and a confluent moist desquamation.

Patient applied StrataXRT during ongoing radiation therapy. After 19 days of topical treatment, a reduction of edema and erythema, and closure of the wound was observed.

Calf muscle cancer

Patient showing a severe RTOG 2 radiation dermatitis with a bright erythema and an inflammation of the scar. No signs of dry desquamation.

Patient applied StrataXRT during ongoing radiation therapy. After 20 days of topical treatment there is no longer a sign of the erythema. The scar shows low inflammatory signs, while the surrounding skin area has persisting depigmentation.
StrataXRT vs Common Treatment Regimen

StrataXRT reduces the severity of radiation induced skin reactions, therefore minimizing the probabilities of not complying with the planned radiation therapy.

**Skin Care Overall Costs During Radiation Therapy Treatment**

<table>
<thead>
<tr>
<th>Extra nursing time needed to cut and adapt dressings</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing time</td>
<td></td>
</tr>
<tr>
<td>Physical dressings</td>
<td></td>
</tr>
<tr>
<td>Burn cream</td>
<td></td>
</tr>
<tr>
<td>Moisturizing cream</td>
<td></td>
</tr>
<tr>
<td>StrataXRT</td>
<td></td>
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<tr>
<td>Common treatments</td>
<td></td>
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</table>

- **StrataXRT**
  - No nursing time
  - Self-applicable by patient
  - Developed for radiation dermatitis
  - Proven clinical efficacy

**How Much StrataXRT is Required**

StrataXRT gel is a unique formulation that requires substantially less product per application than typical moisturizing creams or barrier ointments.

- **StrataXRT 0.35 oz (10g)**
  - contains enough gel for over 1 week of treatment during a standard fractionation plan*
  - applying the gel twice per day.

- **StrataXRT 0.7 oz (20g)**
  - contains enough gel for over 2 weeks of treatment during a standard fractionation plan*
  - applying the gel twice per day.

- **StrataXRT 1.75 oz (50g)**
  - contains enough gel for over 5 weeks of treatment during a standard fractionation plan*
  - applying the gel twice per day.

* Standard fractionation in head and neck cancer treatment is considered to be 6 weeks. 2 weeks post radiation are expected for toxicity peak and 2 weeks more for recovery of the skin. The standard therapy time can therefore extend up to 2 weeks.

**References:**


**Recommended duration of treatment**

StrataXRT is recommended to be applied following the initial radiation dose and should continue to be used for a minimum of 60–90 days (24/7) post-radiation therapy, or until no further improvement is seen. For chronic radiation dermatitis, continued use is recommended until no further improvement is seen.

**Ingredients:**

- Polydimethylsiloxanes, silicones, alkylmethylysiloxanes

**Caution:**

- For external use only. StrataXRT should not be placed in contact with the eyes.
- StrataXRT should not be applied over topical medications unless advised by your physician.
- StrataXRT may stain clothing if not completely dry. Should your radiation dermatitis show signs of infection or failure to heal, consult your physician. If irritation occurs, discontinue use and consult your physician. Not suitable for highly exudative wounds, tunneling wounds or 3rd degree burns. Keep out of the reach of children. Do not use after the expiration (EXP) date printed on the tube.

**STERILE UNTIL OPENED**

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**References:**


**References:**