A new approach in the management of radiation dermatitis

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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. Adjuvant chemotherapy substantially increases the risk to develop severe skin injuries. The introduction of modern mega-voltage treatment machines with skin-sparing capabilities have improved but not eliminated skin toxicities.

How do current therapies rate?

Systematic reviews on the management of radiation dermatitis found no evidence indicating a difference between topical pharmacological treatment and topical non-pharmacological treatment in patients undergoing radiation therapy, except for corticosteroids. Corticosteroids can cause thinning of the skin which can potentially cause skin dehydration. Studies assessing lotions, creams and emulsions (aloe vera, hyaluronic acid, corticosteroids sucralfate) either showed no benefit in managing radiation dermatitis or provided conflicting evidence. Adjuvant chemotherapy substantially increases the risk to develop severe skin injuries. 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>
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<tr>
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<th>StrataXRT scores</th>
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<tr>
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<td>Minimized water loss and optimized skin hydration by means of topical agents</td>
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Radiation therapy – the unwelcome consequence of a life-saving therapy

Radiation therapy is the most effective treatment for most types of cancer. However, it can cause side effects, including radiation dermatitis. 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.

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StrataXRT indicated from the initial radiation dose for the duration of radiation therapy until full skin recovery

StrataXRT is intended to be used under the direction of healthcare practitioners in the management of radiation dermatitis.

StrataXRT is indicated for use on all types of radiation dermatitis, toxic and compromised skin and superficial wounds resulting from radiation therapy. StrataXRT is indicated for the relief of dry, itching, flaking, peeling and irritated skin, as well as the symptomatic relief of pain, redness and heat sensation.

The RTOG scale for radiation dermatitis

The RTOG scale for radiation dermatitis is an assessment tool used to evaluate the severity of skin reactions during radiation therapy. The scale ranges from 0 to 4, with higher scores indicating more severe skin reactions. The RTOG scale is designed to help healthcare professionals monitor and manage skin reactions effectively.

<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>
<th>StrataXRT indicated for use</th>
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<tr>
<td>0</td>
<td>No visible change to skin</td>
<td>Maintain soft, supple, clean, odor free and intact skin.</td>
<td>✓ StrataXRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Redness, inflammation</td>
<td>Maintain soft, supple, clean odor free, intact skin, reduce irritation and promote comfort.</td>
<td>✓ StrataXRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Sensitive skin with bright redness</td>
<td>Maintain soft, supple, clean odor free, intact skin, reduce irritation and promote comfort.</td>
<td>✓ StrataXRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5</td>
<td>Patchy moist desquamation</td>
<td>Reduce the risk of infection, minimize pain and trauma of the skin.</td>
<td>✓ StrataXRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Confluent moist desquamation</td>
<td>Debride the wound. Control associated bleeding and oozing (exudate), minimize effects of wound infection.</td>
<td>✓ StrataXRT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Ulceration, bleeding, necrosis</td>
<td>Debride the wound. Control associated bleeding and oozing (exudate), minimize effects of wound infection.</td>
<td>✓ StrataXRT</td>
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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.

Photos from several patients. 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.”

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StrataXRT as prevention\textsuperscript{16}

StrataXRT helps to preserve the skin’s integrity, by reducing the side effects of ionizing radiation.

- StrataXRT creates a protective film that maintains skin integrity, reduces friction and irritation to the affected site.
- StrataXRT lightly bonds to the stratum corneum, protecting it from excessive sloughing.
- StrataXRT helps to prevent the compromised skin from infections.
- StrataXRT reduces the skin’s acute inflammatory response.
- StrataXRT does not cause bolus effect.\textsuperscript{17,18}

\begin{itemize}
  \item 41.0\% reduced risk of developing grade 2 skin toxicity.\textsuperscript{16}
  \item 49.4\% reduced risk of developing grade 3 skin toxicity.\textsuperscript{16}
\end{itemize}

To be used immediately after the first dose of radiation therapy.

StrataXRT for the treatment of radiation dermatitis\textsuperscript{19}

StrataXRT helps to reduce Trans Epidermal Water Loss (TEWL) 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.
- Reduction of pain, redness and soothing of the exposed skin areas.

\begin{itemize}
  \item In dry desquamation, StrataXRT protects the fragile epidermis and maintains the skin’s integrity, preventing the outmost layers from excessive sloughing.
  \item In moist desquamation, StrataXRT protects the dermal stroma from long term deterioration whilst optimizing the environment for the reparative process and reducing the risk of infection.
\end{itemize}

Why is StrataXRT an innovative product?

- **FILM-FORMING, FULL CONTACT, FLEXIBLE WOUND DRESSING**
  StrataXRT is a flexible, full contact wound dressing that forms a thin film that ensures constant contact with the skin.

- **FROM DAY ONE**
  StrataXRT can be applied from day one of radiation therapy.

- **NO BOLUS EFFECT**
  StrataXRT does not cause a bolus effect.\textsuperscript{17,18}

- **FASTER WOUND HEALING**
  StrataXRT promotes a moist wound healing environment leading to faster re-epithelialization.

- **SYMPTOMATIC RELIEF**
  StrataXRT provides symptomatic relief from itching, burning sensation and discomfort.

- **HYDRATION**
  StrataXRT dries to form a protective layer that is gas permeable and waterproof which hydrates compromised skin areas and superficial wounds.

- **PROTECTION**
  StrataXRT is bacteriostatic, it protects the skin from irritants and microbial invasion while reducing the risk of contact dermatitis.

- **NON-REACTIVE**
  StrataXRT is non-reactive, it has no measurable pH, contains no alcohol, parabens or fragrances, making it suitable for children, and people with sensitive skin.

- **FOR DIFFERENT AREAS**
  StrataXRT is suitable for large surface areas and contoured skin like the breasts, face, back and pelvic area, as well as joints and hairy areas without the need for shaving.

- **LIGHTLY BONDS**
  StrataXRT lightly bonds to the most superficial damaged skin layer.

- **A SMALL AMOUNT GOES A LONG WAY**
  StrataXRT is a unique formulation which requires substantially less product per application than typical creams or gels.
A 197-patient study conducted in Australia investigated the effects of StrataXRT versus 10% Glycerine moisturizer (Sorbolene cream) for preventing and managing radiation dermatitis in patients with head and neck cancer receiving radical radiotherapy.\textsuperscript{16}

StrataXRT is superior to moisturizer in preventing and reducing severity of skin toxicity:

- 41.0% reduced risk of developing grade 2 skin toxicity.
- 49.4% reduced risk of developing grade 3 skin toxicity.
- Lower mean skin toxicity at the end of radiation treatment period.

StrataXRT is superior to moisturizer in delaying severity of skin toxicity:

- Longer period without grade 3 skin toxicity with 75% of patients surviving 6 weeks.
- Median of 4 weeks to reach grade 2 toxicity compared to 3 weeks for moisturizer.

StrataXRT is easy to apply, acceptable, feasible and effective for head and neck cancer patients, even in situations where body hair is present.

A 56-patient study was conducted in South Korea where patients who received radiation therapy were randomly assigned to two groups, StrataXRT versus a cosmetic moisturizer cream containing herbal extracts (X-derm).\textsuperscript{20}

StrataXRT patients had a significantly lower level of erythema (21%) and Trans-Epidermal Water Loss (TEWL) (76%)\textsuperscript{*} at 6 weeks and had lower melanin changes (31%) at 8 weeks when compared to the moisturizer group.

\*not statistically significant

A 5-patient case study series was conducted in Spain to explore the use of StrataXRT for the treatment of radiation dermatitis during concomitant chemotherapy.\textsuperscript{5}

Patients who received StrataXRT were able to continue the therapy uninterrupted instead of being at risk of stopping treatment due to the commonly expected deterioration experienced with adjuvant chemotherapy.

Radiation session 17
Start of treatment with StrataXRT

Radiation session 26
Day 14 using StrataXRT

Radiation session 30
Day 23 using StrataXRT

Radiation session 21
Start of treatment with StrataXRT

Radiation session 31
Day 18 using StrataXRT

Post-radiation day 4
Day 10 using StrataXRT

Weeks
RT

StrataXRT
Moisturizer

StrataXRT
Moisturizer

StrataXRT
Moisturizer

StrataXRT
Moisturizer

StrataXRT
Moisturizer

Cumulative radiation dose
First day of radiation therapy
Application of StrataXRT
Pain
Itching
Burning sensation
Erythema
Hydration

Evolution of RISRAS score during radiation therapy treatment and when applying StrataXRT

Although, radiation dermatitis would only worsen during the RT and until approximately 2 weeks after the end of RT, StrataXRT showed clinical improvement:

- Decreasing of RISRAS score by 17% from the beginning of StrataXRT application until the end of RT.
- Decreasing of RISRAS score by 37.6% from the beginning of StrataXRT application until 10 to 14 days after the end of RT.
StrataXRT versus Mepitel Film®

StrataXRT was shown to be non-inferior to Mepitel Film on the reported outcome measures of moist desquamation and worst grade of acute radiation dermatitis.15

StrataXRT is flexible and allows a perfect adaptation to body surfaces in which common physical sheeting are unsuccessful or impossible to use, such as those with high mobility (joints), high friction (axilla), wet skin (mucosa), and higher hygienic necessities (perineum).9

StrataXRT was also found to be easier to use and improved patient adherence when compared to physical dressings.19

StrataXRT is a more pragmatic choice as Mepitel Film further extended the utilization of scarce nursing resources.

- The average time per application of Mepitel Film was 15 minutes (range 7.5-50 minutes).
- StrataXRT application does not require any nursing time as it is applied by the patient.20
- StrataXRT allows the nursing team to avoid harder to fix, more costly and more time consuming physical dressings. Only a small amount of StrataXRT was necessary and adherence by patients was improved as StrataXRT is transparent when applied.21

StrataXRT does not need to be removed, which can be traumatic for patients when dressings need to be removed and reapplied.19

Three patients developed itching from Mepitel Film with early removal on one patient.21

StrataXRT was shown to be non-inferior to Mepitel Film on the reported outcome measures of moist desquamation and worst grade of acute radiation dermatitis.15

A 64 year old female patient with a bilateral carcinoma with cutaneous infiltration with supraclavicular and multiple axillary adenopathy in Spain. Prior to radiation therapy the patient received 4 cycles of Adriamycin and cyclophosphamide + 12 cycles of paclitaxel chemotherapy. StrataXRT was applied on left breast, standard therapy – on the right breast.25

University Hospital - Fuenlabrada, Madrid, Spain

Effective resource management

StrataXRT is clinically proven to reduce the severity of radiation induced skin reactions improving the patients quality of life6 and minimizing the probabilities of not complying with the planned radiation therapy (StrataXRT reduces treatment breaks). A reduction of patients with radiation-related skin toxicity will:19

- Reduce additional resources associated with radiation therapy discontinuation.
- Benefit the radiation unit’s planning and use of resources.
- Support better health outcomes.

StrataXRT has simplified current dressing protocols which means the average time spent with each patient is significantly reduced.23

Participants using StrataXRT required fewer nursing occasions of service managing radiodermatitis.24

Before and After Cases

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University Hospital - Fuenlabrada, Madrid, Spain

Neoplasm of breast26 - Clinica IMQ Zorrozaurre, Bilbao, Spain

Radiation session 19
Start of treatment with StrataXRT
Post-radiation EOT day 6
Day 7 using StrataXRT
Post-radiation EOT day 13
Day 14 using StrataXRT

Neoplasm of parotid-Face26 - Clinica IMQ Zorrozaurre, Bilbao, Spain

Radiation session 21
Start of treatment with StrataXRT
Post radiation EOT day 2
Day 13 using StrataXRT
Post radiation EOT day 18
Day 29 using StrataXRT

Epidermal carcinoma extending to tonsillar pillar and tonsils5 - Clinica IMQ Zorrozaurre, Bilbao, Spain

Radiation session 23
Day 7 using StrataXRT
Radiation session 31
Day 21 using StrataXRT
Post radiation EOT day 12
Day 35 using StrataXRT
Dosage and Administration

StrataXRT gel is a unique formulation that requires substantially less product per application than typical creams or gels. StrataXRT 1.75 oz (50g) is enough to treat an area of 6×12 inch (15×30 cm) twice per day for 30 days. 0.35oz (10g) of StrataXRT is enough for approximately 1 week of application.

How supplied:

StrataXRT 1.75oz (50g) tube (73661-420-50)

Directions for use

1. Ensure that the affected skin or superficial wound is clean and dry. Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.

2. Apply a very thin layer of StrataXRT directly to the affected area and allow the gel to dry. It will dry in 5 to 6 minutes. 1 min

3. If it takes longer to dry you have probably applied too much. Gently remove the excess with a clean tissue or gauze and allow the drying process to continue.

4. Once dry, StrataXRT may be covered by sunscreen, cosmetics and clothing.

Additional directions

- StrataXRT should be applied once or twice daily to the affected areas or as required to maintain contact with the affected surface.
  - StrataXRT may be re-applied more often to ensure constant contact with the skin, or to reduce symptoms.
  - Washing will likely remove StrataXRT. Re-apply StrataXRT after each wash.
  - Areas with higher hygienic necessities (groin, perineum, anal): StrataXRT should be applied after each urination and bowel movement, on dry and clean skin.
  - For best results StrataXRT should be maintained in continuous contact with the skin (24 hours a day/7 days a week).
  - StrataXRT does not need to be removed prior to radiation therapy.
  - StrataXRT can be used with or without a secondary protective dressing.
  - StrataXRT does not need to be rubbed in or massaged, as it does not penetrate below the level of stratum corneum and will not enhance its effect.
  - StrataXRT can be applied directly to the skin, using the finger, Q-tip etc.

Tips for StrataXRT usage

- StrataXRT may be stored in the refrigerator prior to application for faster relief of the burning sensation that may occur following radiation therapy.
  - If not completely dry, StrataXRT may stain clothing. Normal washing will not remove the product from the clothes. If staining occurs, dry cleaning should be able to remove it without any damaging of the fabric.

StrataXRT and other products

Moisturizers, lotions, burn creams etc. are not required. StrataXRT can be re-applied more often to avoid dry and tight skin feeling, as StrataXRT prevents the water evaporation through the damaged skin that may cause this feeling. Alternatively, a moisturizer can be applied after StrataXRT dries to maintain the first contact of StrataXRT with the skin.

StrataXRT reduces the need for antibiotics.

StrataXRT is bacteriostatic and prevents microbial and bacterial invasion without the risk of contact dermatitis.

StrataXRT reduces the need for corticosteroids.

StrataXRT reduces skin’s acute inflammatory response without side effects of corticosteroids.

Secondary dressing StrataXRT will not absorb exudate. In moist desquamation, StrataXRT should be used in combination with absorbent dressings. StrataXRT should be the first layer of contact with the skin. StrataXRT does not need to dry before applying the secondary dressing.

Additional prescribing information

Therapeutic group: Wound dressing for the management of radiation dermatitis.

Pharmaceutical form: Occlusive, non-resorbable, self-drying and transparent gel.

Description: When used as directed StrataXRT dries to form a protective layer that is gas permeable and waterproof which hydrates and protects compromised skin areas and superficial wounds from chemical and microbial invasion. StrataXRT helps to promote a moist wound healing environment. This moist wound healing environment promotes faster re-epithelialization* and reduces the skin’s acute inflammatory response seen with both dry and moist desquamation.

Warnings: 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. If staining occurs, dry cleaning should be able to remove it without damaging the fabric. For correct storage please reclose the tube tightly with the cap. If irritation occurs, discontinue use and consult your physician. Keep out of the reach of children. Do not use after the expiration (EXP) date printed on the tube. The expiration (EXP) date does not change once the tube has been opened. Do not use if the tube is damaged.

Contraindications: Do not administer to patients with known hypersensitivity to the ingredients of this product.

Side effects: At the time of producing this material, no adverse effects have been reported with the use of StrataXRT.

Drug interactions: None known.

Use in specific populations: No specific population restrictions, StrataXRT is suitable for children and people with sensitive skin.

Storage: Store at room temperature, out of direct sunlight.


IMPORTANT

Due to StrataXRT’s semi-permeable nature:

- StrataXRT may enhance the effect of an active ingredient if StrataXRT is applied over the active ingredient.
- StrataXRT may prevent or reduce absorption of active ingredients if they are applied over StrataXRT.
Filling a StrataXRT prescription

If StrataXRT will be picked up by the patient in an institutional pharmacy associated with your clinic, please share the tear sheet with the patient so they can receive the lowest co-pay possible.

Otherwise, StrataXRT can be filled by Truepill pharmacy. Please share the tear sheet with the patient and follow the instructions below.

Your patient will receive StrataXRT as you prescribed it with free delivery from Truepill pharmacy.

1. Send script to Truepill
   - eRx: Truepill (Hayward, CA) or NCPDP: 5660091
   - Fax: 518-734-0053
   - Verbal: 650-353-5495 | 855-910-8606

   To minimize callbacks, include:
   - Patient’s current mobile number
   - Patient’s email
   - Patient insurance information
   - Tried/failed meds or chart notes
   - Allergies
   - ICD-10 code

2. Provide tear sheet to patient
   Patient will receive a phone call or text with instructions on how to proceed with the prescription.

3. Submit any prior auths in CoverMyMeds with the key provided by Truepill.
   In the event CoverMyMeds does not process PA the pharmacy will notify you.

Questions about prescription? Contact Truepill’s HCP support team at: 650-353-5495 | 855-910-8606 or operations_support@truepill.com

Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane. STERILE UNTIL OPENED.

References:
16. Chan et al. (2019), Radiotherapy and Oncology, 139, pp.72-78.
17. Data on file, 2018 (Dr. Ekberg, University Hospital Basel, Basel, Switzerland).
21. Data on file, 2019 (Chao. M. Austin Hospital, University of Melbourne, Australia).