StrataXRT®

for the prevention and treatment
of radiation dermatitis

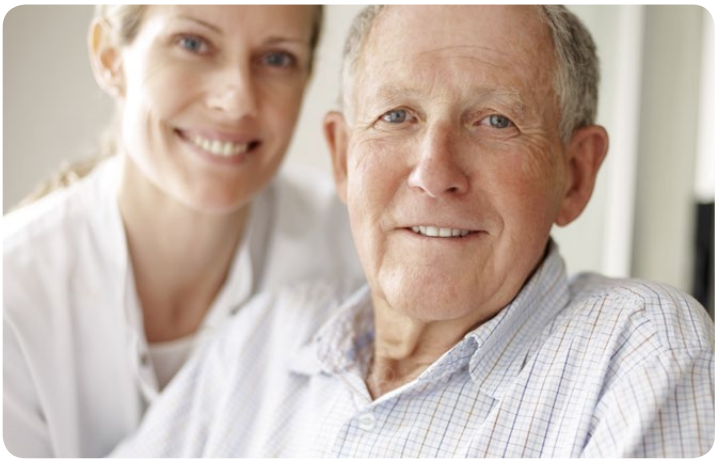
StrataXRT – an innovative, flexible wound dressing for the prevention and treatment of radiation dermatitis

Stratpharma
Switzerland

Radiation dermatitis – the unwelcome consequence of a life-saving therapy

Acute radiation-induced skin reactions are an inevitable consequence of radiation therapy and occur in up to 95 % of patients receiving treatment to the breast, groins or perineum.[1,2,3]
Acute skin reactions range from erythema through dry desquamation to 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 can compromise patient outcomes.**[3]

- **Up to 50–60 % of patients receiving treatment for cancer will undergo radiation therapy at some stage in their illness.**[1,4,5]
- **The introduction of modern mega-voltage treatment machines, with skin-sparing capabilities has ameliorated but not eliminated skin toxicities.**[6]
- **Studies assessing lotions, creams, or emulsions (aloe vera, hyaluronic acid, corticosteroids, sucralfate) either proved no benefit in preventing or managing radiation dermatitis or provided conflicting evidence.**[7,8,9]



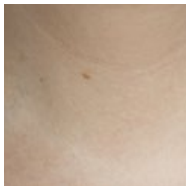
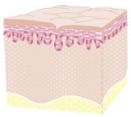
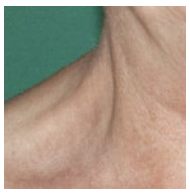
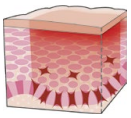
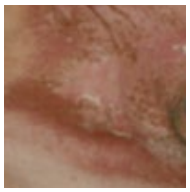
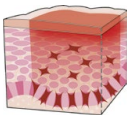
Consensus goals of care for skin reactions during radiation therapy

Initial maintenance of skin integrity
Reduced potential of further exacerbation of skin reaction
Minimized water loss and optimized skin hydration by means of topical agents
Promotion of comfort and compliance
Reduction of pain and pruritius without causing a bolus effect
Control of bleeding, odor and excessive exudate (in combination with secondary dressings)
Provides ideal environment for rapid healing and re-epithelialization
Promotion of moist wound healing environment where skin is broken
Protection from trauma & friction
Prevention of infection

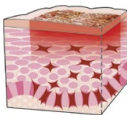
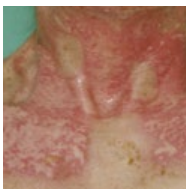
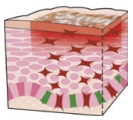
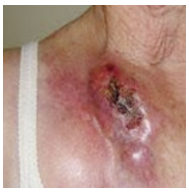
It is essential that any damage is minimized by ensuring that interventions are based upon best practice and supported by evidence based guidelines.[2]

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 reaction based on assessment of the skin and the RTOG score.

Assessment/ observation	Effects on skin cells	Treatment goals
		**RTOG 0** Maintain soft, supple, clean, odour free and intact skin.
		**RTOG 1** Maintain soft, supple, clean odor free, intact skin, reduce irritation and promote comfort.
		**RTOG 2** Promote hydrated skin, comfort and maintain skin integrity. Reduce itch, pain, soreness and discomfort.

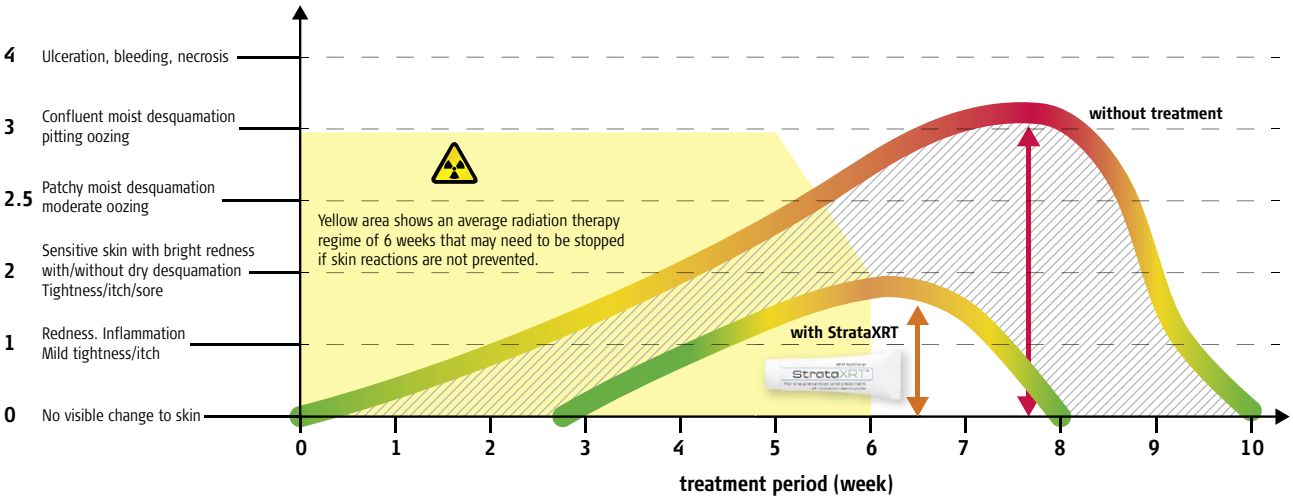
Images do not correspond to the same patient.

Assessment/ observation	Effects on skin cells	Treatment goals
		**RTOG 2.5** Reduce risk of complications of further trauma and infection. Reduce pain, soreness and discomfort.[13]
		**RTOG 3** Reduce the risk of infection, minimize pain and trauma to the skin.
		**RTOG *4*** Debride the wound. To control associated bleeding and oozing (exudate), minimize effects of wound infection.

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".

How can the progression along the RTOG scale during radiation therapy be prevented?

RTOG scale 0–4: symptoms and skin changes



- **Area between the curves represents the prophylactic effect of StrataXRT.**
- **Onset of early symptoms of radiation dermatitis are delayed.**
- **Moist desquamation is prevented.**
- **Peak of toxicity occurs earlier.**
- **Overall symptoms are less acute.**
- **Irradiated site heals faster.**

Clinical results with StrataXRT

Case Study Korea, 2015

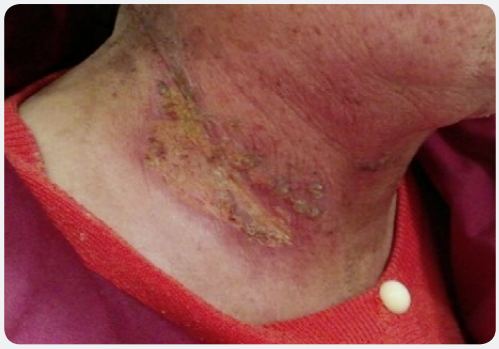
Yonsei University Health System, Severance Hospital, Korea

A case series study was performed for treating different RTOG stages of toxicity. Patients and nurses reported an overall improvement and reduced itching and pain symptoms. Patients admired the transparency of StrataXRT once dry while protecting the affected area.[11]

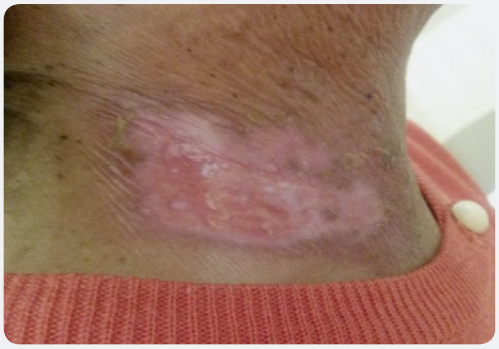
Case Study Spain, 2015*

*Location of the investigation not disclosed due to participation in currently ongoing clinical trial

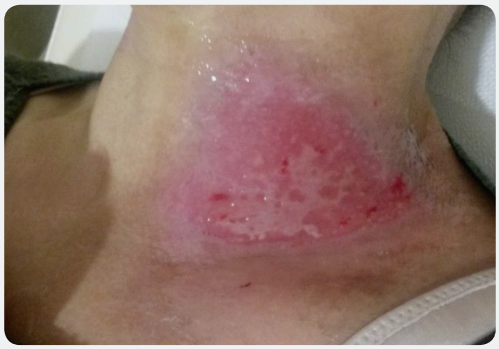
Prior to start a phase IV clinical trial, several patients were treated with StrataXRT at a case series level. Patients reported excellent skin elasticity improvements and the nursing department remarked the improved RTOG toxicity even during ongoing radiation therapy.[12]



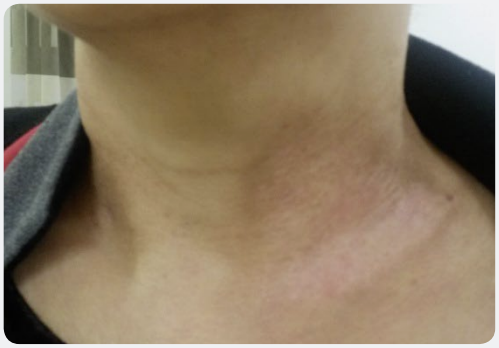
After week 1 of radiation therapy (RTOG 2.5)



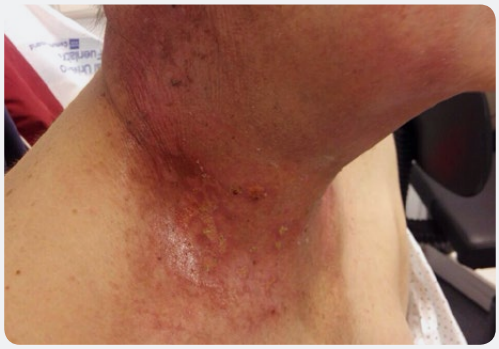
6 days after treatment with StrataXRT[11]



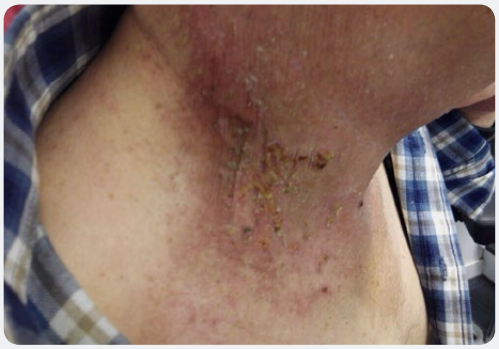
After week 7 of radiation therapy (RTOG 2.5)



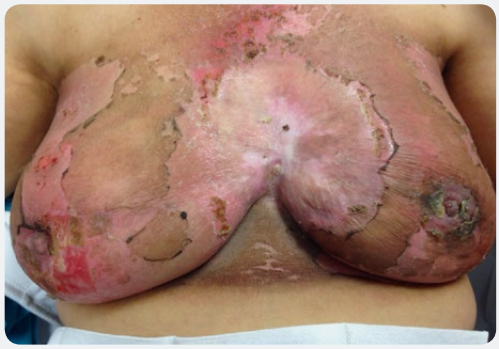
7 days after treatment with StrataXRT[11]



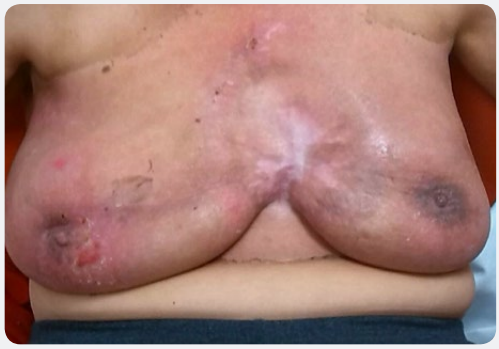
During radiation therapy, week not recorded (RTOG 2.5)



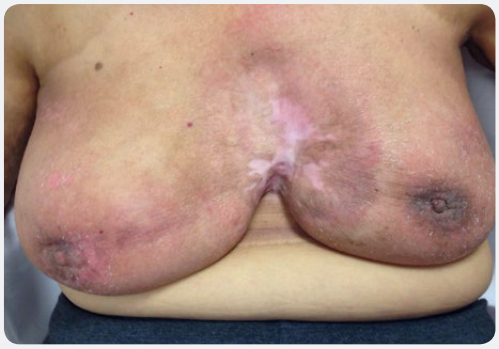
2 days after treatment with StrataXRT[12]



After week 4 of radiation therapy with concomitant chemotherapy (RTOG 2.5)



1 week after treatment with StrataXRT

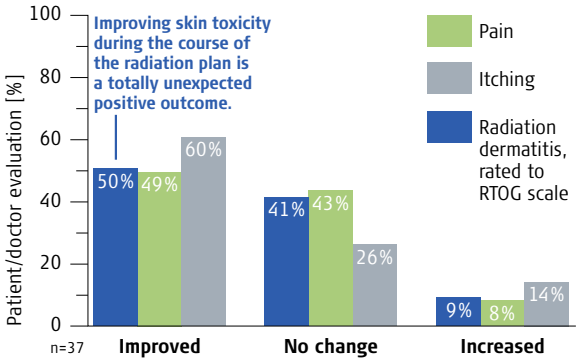


2 weeks after treatment with StrataXRT[12]

Prague Study 2012

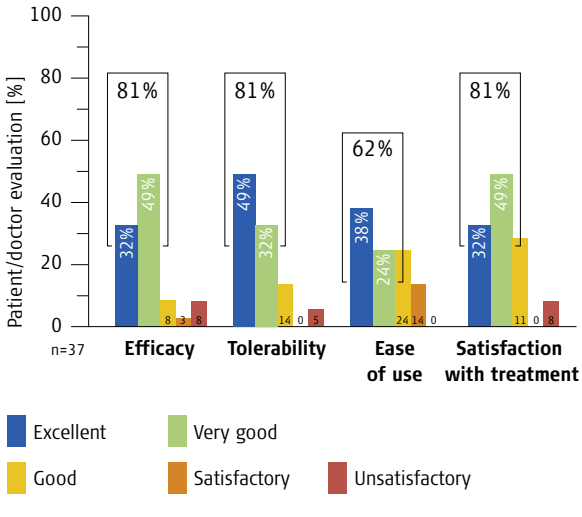
In a multicenter study performed in Prague (2012), 37 patients were treated with StrataXRT during their radiation therapy.[10]

Assessment of radiation dermatitis, pain and itching at irradiated site during treatment with StrataXRT



Patients were treated with StrataXRT continously during radiation therapy until an average of 7.5 days post radiation therapy.

Patient and doctor evaluation of StrataXRT



StrataXRT as prophylaxis

StrataXRT gel is bacteriostatic and inert

StrataXRT helps to preserve the skins integrity, by reducing the side effects of ionizing radiation

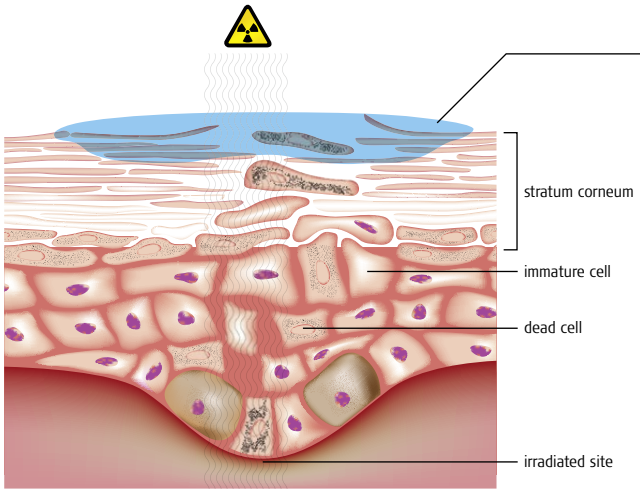
- StrataXRT creates a protective film that maintains skin integrity and reduces trauma and irritation to the affected site.
- StrataXRT protects the skin from excessive sloughing of the stratum corneum.
- StrataXRT helps to prevent the compromised skin from infections.
- StrataXRT provides a semi-occlusive coverage for optimal hydration of injured area.
- StrataXRT reduces the skin's acute inflammatory response.
- StrataXRT does not cause bolus effect.

To be used immediately after first dose radiation therapy or on first/second degree burns

StrataXRT for the treatment of radiation dermatitis

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

- Faster re-epithelialisation of the skin post therapy.
- Relief of low grade cutaneous changes such as dry, itching, flaking, peeling and irritated skin.
- StrataXRT reduces pain, redness and heat to help soothe exposed areas in more severe inflammatory changes.



In dry desquamation, StrataXRT protects the fragile epidermis and maintains the skin's integrity, preventing the outmost layers from excessive sloughing.

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.

StrataXRT was developed for use on:

- **Radiation dermatitis**
- **First and second degree burns**
- **Superficial wounds**
- **Irritated, dry and itchy skin**
- **Red and inflamed skin**
- **Toxic and compromised skin**

StrataXRT Pharmacoeconomics

Pharmacoeconomics are calculated based on several criteria:

- **Incidence of severe radiation dermatitis cases**
- **Product cost**
- **Product usage**
- **Nursing time**

Improving the incidence and healing of moist desquamation reduce the number and duration of treatment interruptions, and reduce the need for specific therapies and/or hospital specialties.

Treatment interruptions may be necessary if skin reactions are severe. The consequences are:

- **Radiation machine rescheduling**
- **Other patients fractionation plans might be affected**
- **Patients are not receiving treatment for their cancer during treatment interruptions**

Severe reactions like moist desquamation need extra nursing time, therapy cost and other hospital specialties might need to intervene.

Cost of preventive use of StrataXRT vs common treatment regime

StrataXRT costs **Preventive treatment**	Moisturizer + burns cream + physical dressing costs **Symptomatic treatment**
Nursing time: reduced due to ease of use. Patients apply StrataXRT at home.	**Nursing time:** long due to dressing changes and adaptation (cutting and shaping to fit body contours and folds) in every session.
Efficacy: StrataXRT is efficacious both for prevention and treatment.	**Efficacy:** moisturizers and burn creams are not efficacious for treating and preventing radiation dermatitis. Physical dressings are only applied after the skin toxicity is high.
Preventive effect is achieved, if StrataXRT is used as directed and applied immediately after the first dose of radiation therapy.	**Preventive effect is not achieved.** The algorythm is based on treating the signs of radiation dermatitis as soon as they appear.
Yield: 1 tube of StrataXRT 50 g is enough to cover an area of 12×15 cm twice per day for over 75 days. 1 tube of StrataXRT 20 g is enough to cover an area of 12×15 cm twice per day for over 30 days. **1 gram of StrataXRT yields the same coverage area as 4.5 physical dressings (12×15 cm).**	**Yield:** Standard physical dressings cover a limited area of 12×15 cm but need to be changed daily affecting the product yield. Moisturizers and burn creams need to be applied frequently in higher volumes.

StrataXRT the innovative, flexible wound dressing for the prevention and treatment of radiation dermatitis

StrataXRT film-forming gel dries as a thin, flexible and protective layer that is gas permeable and waterproof.

StrataXRT is inert and has no measurable pH value.

- Does not affect the fragile acid mantle of the skin

StrataXRT is designed specifically for the use on open wounds and compromised skin.

- Can be used immediately after radiation treatment or on first and second degree burns
- Does not cause bolus effect
- StrataXRT gel is bacteriostatic and inert

StratXRT's self-drying gel formula offers superior ease of use and versatility.

- Transparent
- Easy to use: no dressing changes needed, patients apply StrataXRT at home
- Non-sticky
- Suitable for children and sensitive skin
- Ideal for large or contoured areas including the breast, face, back and pelvic areas
- Suited to joints/hairy areas without need for shaving
- Contains no alcohol, parabens or fragrances

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

StrataXRT 50 g size 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.

www.strataxrt.com

Directions for use

- 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.
- Apply a very thin layer of StrataXRT directly to the affected area and allow the gel to dry.
- StrataXRT should be applied once or twice daily to affected areas or as advised by your physician.
- Once dry, StrataXRT may be covered by sun screen, cosmetics and clothing.
- For best results StrataXRT should be maintained in continuous contact with the skin (24 hrs/day).

When applied correctly to the affected areas, StrataXRT should be dry in 5–6 minutes. 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.

Recommended duration of treatment

StrataXRT is recommended as prophylaxis following the initial radiation dose and should continue to be applied 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.

How much StrataXRT is required?

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

- One 50 g (1.75 oz) tube is enough to treat an area of 12 cm × 15 cm, (5 inch × 6 inch) twice per day for over 75 days.
- One 20 g (0.7 oz) tube is enough to treat an area of 12 cm × 15 cm, (5 inch × 6 inch) twice per day for over 30 days

StrataXRT may also be used in conjunction with other adjunctive treatments to improve overall results. StrataXRT can be used with or without a secondary protective dressing.

Ingredients: Polydimethylsiloxanes, Siloxanes, Alkylmethyl Silicones

References:

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4 Naylor W & Mallett J. European Journal of Oncology Nursing 2001;5(4):221-233
5 López E, Nuñez MI, Guerrero MR, et al. Breast Cancer Res Treat. 2002;73(2):127
6 Hymes S et al. J Am Acad Dermatol. 2006;54(1):28-46
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8 McQuestion. Seminars in Oncology nursing 2006;22(3):163-173
9 Wickline. Oncology nursing forum 2004;31(2):237-244
10 Data on file, Stratpharma AG, Basel, Switzerland, 2012
11 Data on file, Stratpharma AG, Basel, Switzerland, 2015
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13 Porock D. European Journal of Cancer Care. 1998

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