Dressings with Safetac® technology:

Prevention and management of radiotherapy-induced skin damage

Clinical research data

Mölnlycke®

Abstract

Radiotherapy-induced skin damage (RISD) can reduce patient quality of life as a result of pain and discomfort, poor cosmesis, loss of sleep, anxiety, and decreased functional and social ability. Moist desquamation is the main cause of patient suffering, leading to pain and discomfort whilst also increasing the risk of infection. Safetac® (soft silicone) technology is incorporated into the design of various dressing types manufactured by Mölnlycke Health Care including wound contact layers, absorbent foam dressings, exudate transfer dressings, film dressings, post-operative dressings, scar management dressings and fixation tapes. Dressings with Safetac have been demonstrated to minimise dressing-related trauma and pain when used in the management of a diverse range of wound types. Numerous randomised controlled trials (RCTs) have demonstrated the ability of dressings with Safetac to prevent (Mepitel® Film) and successfully manage (Mepilex® Lite) RISD.

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Introduction to radiotherapy-induced skin damage (RISD)

Radiotherapy is the primary treatment for many types of cancer (Wei et al, 2019); high energy X-rays (photons) and other forms of ionising radiation are used. Ionising radiation directly or indirectly damages the structures and chemicals within cells of a target area. Radiotherapy is based on the concept that cells in healthy tissues are much more likely to recover and repopulate than the cancer cells in the tumour (Morgan, 2014). Yet, radiotherapy-induced skin damage (RISD), also termed radiotherapy-induced dermatitis, radiation-induced dermatitis, radiation dermatitis or radiodermatitis, is one of the main adverse events associated with radiotherapy, and it can damage the healthy tissues in both the short and long term (Wei et al, 2019). Manifestations of RISD include erythema, pigmentation and dry desquamation; severe radiodermatitis can cause moist desquamation, pain and decreased quality of life (QoL) (Yee et al, 2021). **Figure 1** provides a simplified schematic of the process leading to RISD.

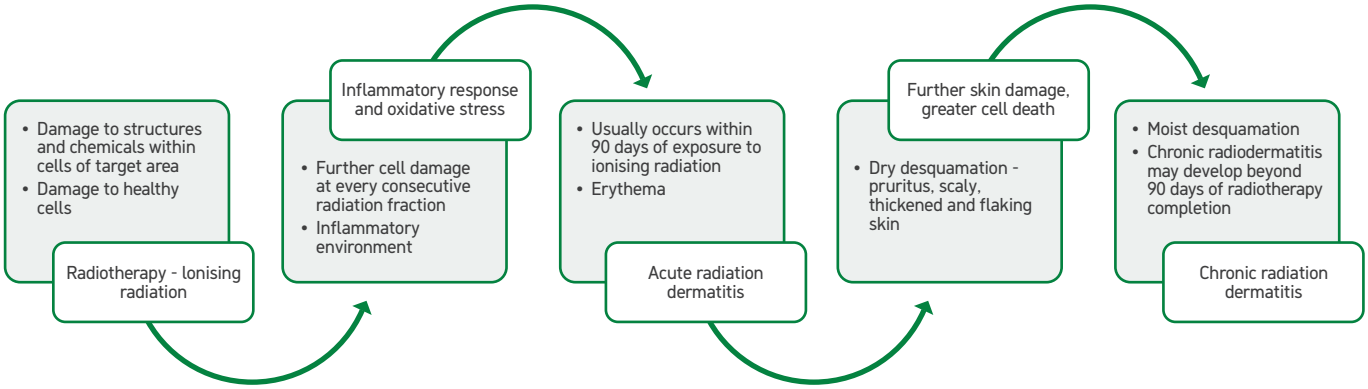

Figure 1. Simplified schematic of the process leading to radiotherapy-induced skin damage

RISD affects approximately 90-95% of patients undergoing radiotherapy (Zasadziński et al, 2022). The severity of the reactions relates to the biological damage done to the dermis and epidermis during radiotherapy (Morgan, 2014). The extent of tissue damage depends on a range of internal (patient-related) and external (e.g. treatment-related) factors (Hegedus et al, 2017; Behroozian et al, 2021; Wei et al, 2019; Yee et al, 2021; Robijns et al, 2023; Finkelstein et al, 2022).

RISD is normally categorised by versions of internationally recognised systems that typically grade the severity of the dermatitis from 0-4 or 0-5, with the higher grades indicative of more severe reactions. The categorisations are part of broader toxicity grading systems, such as one developed by the **Radiation Therapy Oncology Group (RTOG)**, in conjunction with the **European Organization for Research and Treatment of Cancer (EORTC)** (Cox et al, 1995), and another referred to as the **Common Terminology Criteria for Adverse Events (CTCAE)** (Spampinato et al, 2025) (**Table 1**).

Table 1. Comparison of two commonly used systems for the grading of radiotherapy-induced skin damage

Grade	Radiation Therapy Oncology Group (RTOG) / European Organization for Research and Treatment of Cancer (EORTC)	Common Terminology Criteria for Adverse Events (CTCAE)
0	No change over baseline	Not defined
1	Faint erythema / dry desquamation	Faint erythema / dry desquamation
2	Moderate to brisk erythema / patchy moist desquamation, mostly in skin folds and creases / moderate oedema	Moderate to brisk erythema / patchy moist desquamation, mostly in skin folds and creases / moderate oedema
3	Confluent moist desquamation (not limited to skin folds) / pitting oedema	Moist desquamation in areas 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	Life-threatening consequences / skin necrosis or ulceration of full thickness dermis / spontaneous bleeding requiring intervention
5	Not defined	Death related to radiation dermatitis (extremely rare)

A third commonly used tool is the **Radiation-Induced Skin Reaction Assessment Scale (RISRAS)**. This was designed to address limitations with the RTOG/EORTC and CTCAE scales by incorporating both clinician-assessed objective signs and patient-reported symptoms. The clinician-assessed parameters are erythema and dry desquamation (using a zero-to-four-point scale) and moist desquamation and necrosis (assessed on a scale having values 0, 2.5, 5.0. 7.5 and 10). The patient-assessed parameters are tenderness and discomfort or pain, itch, burning sensation and the extent to which skin reactions affect daily activities (assessed on a scale of 'not at all', 'a little', 'quite a bit' and 'very much'). The total RISRAS score is determined by the summation of the clinician and patient scores (Noble-Adams, 1999).

Challenges

RISD can have a significant patient impact (Wei et al, 2019; Behroozian et al, 2021); these skin reactions can negatively influence patient QoL as a result of pain and discomfort, poor cosmesis, loss of sleep, anxiety, and decreased functional and social ability (Morgan, 2014; Wei et al, 2019; Behroozian et al, 2021). Moist desquamation is the main cause of patient suffering, leading to pain and discomfort whilst also increasing the risk of infection (Wei et al, 2019). Moist desquamation reactions are not only painful but also provide an environment conducive to infection (MacBride et al, 2008). Furthermore, the onset of RISD and associated symptoms may increase the risk of treatment interruptions and non-compliance, and thus progress of cancer treatment, which can in turn increase the likelihood of disease recurrence, increase late radiation-related side effects, and decrease overall survival (Wei et al, 2019; Behroozian et al, 2021; Zasadziński et al, 2022; MacBride et al, 2008; Yee et al, 2021; Finkelstein et al, 2022). **Figure 2** provides a simplistic schematic of the impact that RISD can have on the patient.

A Canada-based research group completed a study involving 1093 patients to evaluate the impact of patient-related and treatment-related characteristics, including body mass index (BMI), surgery type, prior chemotherapy, smoking status and radiotherapy skin dose, on the development of RISD. Results highlighted several predictive factors for RISD symptoms including erythema, oedema, desquamation, pain and bleeding. High BMI, high tissue volume irradiated by tangential fields, conventional fractionation (50 Gy/25), and addition of a boost or bolus were all significant factors that enhance skin reaction severity among breast cancer patients. (Behroozian et al, 2021).

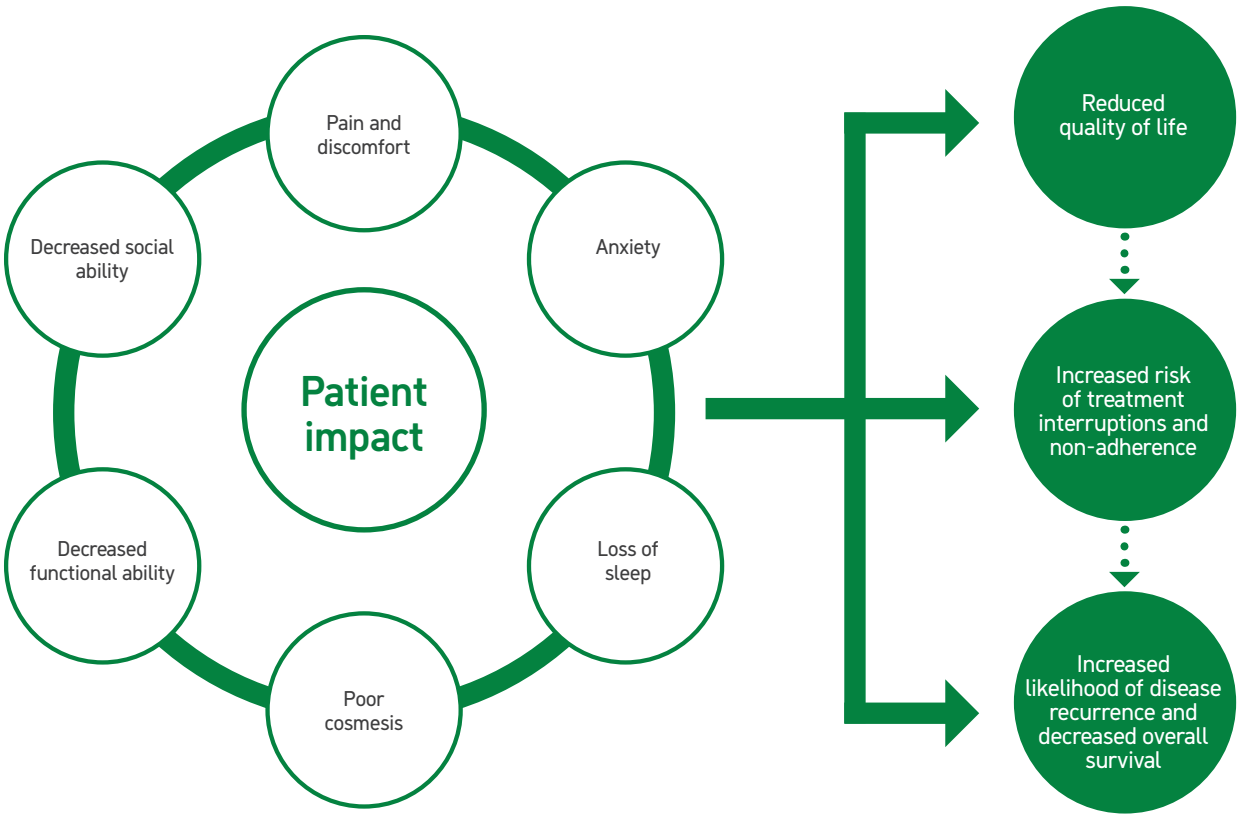

Figure 2. Impact of radiotherapy-induced skin damage on the patient

Role of dressings in the prevention and management of RISD

Various types of dressings may be used either as RISD prophylaxis (from the beginning of radiation therapy) or as a management method (applied at the onset of signs of skin damage) (Zasadziński et al, 2022). Of note, the application of a protective layer is likely to be more effective when applied from the very beginning of radiotherapy in comparison to applying the dressing once RISD is visible (Herst et al, 2014). Furthermore, application technique must be considered; the dressing must be applied correctly with minimal overlapping and should be applied with the patient in radiotherapy treatment position (Herst et al, 2014). The management of RISD using dressings is also multifaceted and requires considerations such as whether the addition of certain materials (e.g. thick foam dressings) would lead to changes in radiotherapy dose distribution (Zasadziński et al, 2022).

The authors of a 2020 systematic review and meta-analysis concluded that, at the time of their publication, overall research in the area of RISD prevention and management provided low to moderate evidence on interventions. However, the analysis identified that semipermeable dressings have a moderate protective effect on the development of grade 2 or higher RISD and on the development of moist desquamation. The analysed studies also revealed minimisation of patient-reported symptoms – tenderness, discomfort, pain and pruritus. A beneficial effect was also highlighted in terms of QoL, although clinical significance was deemed likely to be small (Ginex et al, 2020).

There is limited consensus around the management and prevention strategies for RISD. According to an international review panel, the limited consensus can be attributed to a number of factors - limited high-quality data from robust clinical trials, heterogeneity in study design, high variability in outcome measures and variability in interventions used to manage RISDs. The same group reviewed international guidelines published between 2010 and 2021, including those of the Multinational Association for Supportive Care in Cancer (MASCC), British Columbia Cancer Agency (BCCA), Cancer Care Manitoba (CCMB), Oncology Nursing Society (ONS), Society and College of Radiographers (SCoR) and International Society of Nurses in Cancer Care (ISNCC). They noted only moderate concordance of guideline recommendations across the different organisations. However, BCCA, CCMB, SCoR and ISNCC were found to be in agreement regarding the ability of silicone-based dressings to reduce trauma from moist desquamation, although there was limited consensus on the use of other barrier films or dressings. The authors commented that, as new evidence becomes available, new guidelines must be generated and implemented into practice to optimise patient outcomes (Finkelstein et al, 2022).

Film dressings can be applied directly to the skin or wound, providing protection from friction and excess moisture by providing a semi-permeable mechanical barrier between the basal skin layer and any potential trauma (Dejonckheere et al, 2023; Herst, 2014). The use of barrier films as a protective layer in patients undergoing radiotherapy of the breast or chest wall are of particular interest given RISD (and especially moist desquamation) has a predilection for areas prone to friction such as the axilla and inframammary fold (Dejonckheere et al, 2023). Of note, patients receiving chest wall radiotherapy and patients with large breasts are especially sensitive to developing more severe skin reactions (Wan et al, 2019). Furthermore, film dressings typically have an insignificant bolus effect and have high patient tolerability and comfort (Yee et al, 2021; Dejonckheere et al, 2023). Indeed, tests have confirmed that
Mepitel Film has a negligible bolus effect (Yee et al, 2021).

The selection of dressings that are known to minimise trauma and pain to the patient on removal and allow for infrequent dressing changes is an important consideration for all the oncology-related wound types described above and below (Niculescu et al, 2024).

Introduction to Safetac

There is a predisposition for some modern dressings with traditional adhesive systems to inflict damage on delicate wound tissue or frail peri-wound skin (Charlesworth et al, 2014; Matsumura et al, 2014). A challenge for the clinician, therefore, is to identify dressings that minimise or even negate dressing-related trauma. Safetac technology is based on soft silicone, a material that readily adheres to intact dry skin and remains in place on the surface of a moist wound or damaged surrounding skin without adhering to these fragile tissues. Consequently, dressings with Safetac technology can be repeatedly applied and re-applied without causing damage to the wound or stripping the surrounding skin (Cutting, 2008). The gentle but effective seal that forms between the intact skin and a dressing with Safetac technology inhibits the movement of exudate from the wound into the surrounding area, thereby helping to prevent moisture-related damage (e.g. maceration) of the peri-wound region (White, 2005).

Numerous studies involving healthy volunteers (Dykes et al, 2001; Dykes, 2007; Waring et al, 2008; Waring et al, 2011) and patients with wounds (Zillmer et al, 2006) have confirmed the ability of dressings with Safetac to be less traumatic on removal than dressings with other adhesive systems. By preventing trauma to the wound and peri-wound region on removal, dressings with Safetac minimise pain at dressing changes (David et al, 2018; Tang et al,2015; Woo et al, 2009).

The next section of this document summarises numerous clinical studies that evaluated the use of dressings with Safetac in the prevention and management of RISD. Details of the dressings evaluated in those studies are given in **Table 2** below.

Table 2. Dressings with Safetac evaluated in clinical studies for the prevention and management of RISD

Dressing	Type	Composition	Uses
Mepitel Film 	Film dressing	Polyurethane film coated with a Safetac wound contact layer	For the protection of fragile and sensitive skin. Can also be used as a secondary dressing for fixating dressings or as a landing zone for aggressive adhesive tapes to secure devices to the skin. Also used as a protective dressing over intravenous devices secured with adhesive tapes or sutures
Mepilex Lite 	Foam dressing	Safetac wound contact layer; a thin, flexible absorbent pad (polyurethane foam); and a vapour-permeable backing film (polyurethane)	For use on a wide range of non-to-low exuding wound types to absorb excess exudate (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin and to prevent skin damaged under medical devices
Mepilex Transfer 	Exudate transfer dressing	Safetac wound contact layer; a flexible absorbent pad (polyurethane foam)	For use on a wide range of exuding wound types to transfer exudate to secondary absorbent dressings (reducing the risk of maceration), while maintaining a moist wound environment and minimising dressing-related trauma and pain at dressing changes. It can be left in place for several days (depending on the nature and condition of the wound). Can also be used to protect compromised/fragile skin
Mepitel 	Wound contact layer	Transparent and flexible polyamide net coated on both sides with Safetac	For use on a wide range of exuding wounds. It can be left in place for up to 14 days (depending on the nature and condition of the wound), during which its open mesh structure allows exudate to pass into secondary absorbent dressings that can be changed as required, thereby minimising disturbance to the wound. The open structure also enables topical preparations to be delivered to the wound with Mepitel in place

Evidence for dressings with Safetac

Published in 2023, a systematic review with meta-analysis explored the efficacy of barrier films and dressings in preventing RISD and their impact on related symptoms. Data from 25 studies were pooled and analysed, including five RCTs (Herst et al, 2014; Møller et al, 2018; Wooding et al, 2018; Rades et al, 2019; Yan et al, 2020) that assessed Mepitel Film in RISD prevention. Despite identifying some limitations (particularly relating to the quality of evidence available and study heterogeneity), the authors highlighted that the film dressings can be expected to significantly reduce RISD clinical signs in **breast cancer** and **head and neck cancer** patients (Robijns et al, 2023).

Film dressings in the prevention and management of radiotherapy-induced skin damage in breast cancer patients

A systematic review and network meta-analysis of RCTs was undertaken to investigate the effectiveness of barrier films for the prevention of **breast** RISD. Despite limitations with regards to study design, patient populations and resulting interpretability of research findings, the authors were able to identify Mepitel Film and one other film dressing as the only products that have been shown (in studies that allowed pooling of results) to significantly improve clinician-reported outcomes and patient-reported outcomes, compared to standard of care. Commenting on the benefits of using film dressings to prevent severe RISD, the authors believe that such dressings may be cost-effective in settings with the relevant funds and resources, although a formal cost-effectiveness analysis would be required to confirm this (Wong et al, 2024).

Another systematic review and meta-analysis of RCTs, the results of which were published in 2023, concluded that barrier films are an excellent tool for use in the prevention of RISD among patients receiving **whole-breast** or **chest wall** radiotherapy (Dejonckheere et al, 2023). Of the five studies analysed, three involved the use of Mepitel Film (Herst et al, 2014; Møller et al, 2018; Behroozian et al, 2023). Details of these and other relevant studies are summarised below and in **Table 3.**

Table 3. Prevention and management of radiotherapy-induced skin damage – film dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Valcarenghi et al, 2025 RCT Switzerland	**Subjects:** 154 (age range not specified) **Radiotherapy:** Whole breast plus boost irradiation **Setting:** Oncology centres (n=2)	**Safetac:** Mepitel Film (n=75) **Comparator:** Aqueous-urea cream (beginning of radiotherapy); either SSD or SSD with HA (at onset of moist desquamation) (n=79)	Occurrence of moist desquamation (RTOG grade ≥2)	RTOG ≥2 in 9.5% of Mepitel Film group, compared to 13.9% of comparator group (p=0.393). Longer median time to appearance of RTOG >0 in Mepitel Film group (p=0.035): - Mepitel Film: 26 days - Comparator: 21 days Shorter median time to recovery from RTOG >1 in Mepitel Film group (p=0.027): - Mepitel Film: 17 days - Comparator: 32 days
Behroozian et al, 2023 RCT	**Subjects:** 376 (age range 22-90 years) **Radiotherapy:** Breast / chest wall ± regional lymph node irradiation **Setting:** Oncology centres (n=3)	**Safetac:** Mepitel Film (n=251) **Comparators:** Aqueous cream (n=125)	Occurrence of RISD grade 2 or 3 (CTCAE)	Lower incidence of grade 2 or 3 RISD in Mepitel Film group (p<0.0001): - Mepitel Film: 15.5% (n=39) - Comparator: 45.6% (n=57)
			RISD severity (RISRAS / SSA)	Lower mean total RISRAS scores in Mepitel Film group (p<0.001): - Mepitel Film: 4.0 - Comparator: 5.9 Patient-assessed SSA scores: significantly lower for Mepitel Film than comparator regimen for blistering/peeling (p=0.009), erythema (p=0.001), pigmentation (p<0.0001) and oedema (p=0.03) Clinician-assessed SSA scores: significantly lower for Mepitel Film than comparator regimen for pain/soreness (p=0.0009), blistering/peeling (p=0.009), erythema (p<0.0001) and pigmentation (p=0.001).
Tse et al, 2026 Cost-effectiveness analysis Canada			Cost-effectiveness	Mepitel Film was cost-effective in preventing grade 2 or higher RISD, as compared with comparator; ICER of CAD 3366 per QALY gained (ICER of CAD 2823 per QALY gained when indirect costs included). Probabilistic sensitivity analysis confirmed that Mepitel Film demonstrates 100% probability of cost-effectiveness at a $50,000 per QALY threshold.

Table 3 (continued). Prevention and management of radiotherapy-induced skin damage – film dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Corbin et al, 2025 RCT United States of America	**Subjects:** 208 (age: median 53 years) **Radiotherapy:** Fractionated post-mastectomy radiation **Setting:** Oncology centres	**Safetac:** Mepitel Film (n=143) **Comparator:** Institutional standard of care (SoC) (n=65)	RISD (modified RISRAS) Adverse events	Lower AUCs (estimated from repeated measures (means) mixed model using the patient completed symptom scale of the modified RISRAS scale during and after radiotherapy (1-2 weeks and 3-months) in Mepitel Film group (p=0.012): - Mepitel Film: 33.88 - Comparator: 45.10 Lower modified RISRAS scores during radiotherapy (weeks 4, 5 and 6) and post-radiotherapy (7-14 days) in Mepitel Film group (p = 0.0267). Lower combined patient and provider modified RISRAS scores in Mepitel Film group (AUC difference -16.10; p =0.011). Fewer grade 2 or 3+ reactions in Mepitel Film group (p=0.005): - Mepitel Film: 25.2% - Comparator: 44.6% No significant difference between Mepitel Film and comparator groups in terms of acute acneiform rash (1.4% vs 1.54%), pruritus (9.1% vs 6.2%) or skin infection (4.2% vs 0%). No grade 4 or 5 adverse events (AEs) were reported.
Møller et al, 2018 RCT (intra-patient) Denmark	**Subjects:** 79 (age range 31-82 years) **Radiotherapy:** Breast / chest wall ± regional lymph node irradiation **Setting:** Oncology centres (n=3)	**Safetac:** Mepitel Film **Comparator:** Skin care regime (daily washing, moisturising lotion and / or lotion with glucocorticoids for itching) Breast / chest wall divided into halves for randomisation to either Mepitel Film or skin care regime	PREMs / PROMs RISD severity (RTOG / EORTC)	Less pain (p<0.001), itching (p=0.005), burning sensation (p=0.005), oedema (p=0.017) and sensitivity (p<0.001) reported by patients in Mepitel Film group, compared to comparator group. 76% of patients stated that they would have preferred Mepitel Film on the entire treatment area (p<0.001) and 85% would have preferred the film dressing as a standard treatment option (p<0.001). Significantly less RISD in Mepitel Film group at last day of radiotherapy among mastectomy patients (p=0.005), although no significant difference between groups 14 days post-radiotherapy.
Yan et al, 2020 RCT (intra-patient) China	**Subjects:** 39 (age range 37-69 years) including 11 Chinese patients from Wooding et al (2018) **Radiotherapy:** Bilateral lymph nodes in neck irradiation **Setting:** Oncology centre	**Safetac:** Mepitel Film **Comparator:** Moisturising cream Neck divided into halves for randomisation to either Mepitel Film or moisturising cream	RISD severity (RISRAS / expanded RTOG) Patient preference	Compared to comparator product, Mepitel Film decreased combined RISRAS score by 30% (p<0.001). Compared to comparator product, Mepitel Film decreased moist desquamation rates by 41% (p<0.001). 80% of patients preferred Mepitel Film over the comparator product.
Wooding et al, 2018 RCT (intra-patient) New Zealand, China	**Subjects:** 33 (age range not specified) **Radiotherapy or radio(chemo)therapy:** head and neck irradiation **Setting:** Oncology centres - New Zealand cohort (n=22): 11 complied with management protocol; 11 complied with prevention protocol - China cohort (n=11): all followed prevention protocol	**Safetac:** Mepitel Film **Comparator:** Moisturising cream Neck divided into halves for randomisation to either Mepitel Film or moisturising cream	RISD severity (RISRAS, expanded RTOG) [Data for management and prophylactic protocols pooled]	Compared to comparator product, Mepitel Film decreased overall RISD severity by 29% in the China cohort (p<0.003) and by 27% in the New Zealand cohort (p<0.001). Compared to comparator product, Mepitel Film decreased moist desquamation rates by 37% in the China cohort and by 28% in the New Zealand cohort.

Herst et al, 2014 RCT (intra-patient) New Zealand	**Subjects:** 78 (age range 30-94 years) **Radiotherapy:** Breast / chest wall ± regional lymph node irradiation **Setting:** Oncology centre	**Safetac:** Mepitel Film **Comparator:** Aqueous cream Breast / chest wall divided into medial and lateral halves for randomisation to either Mepitel Film or aqueous cream	Occurrence of moist desquamation (RTOG) Skin reaction severity (RISRAS)	RTOG grades: - Mepitel Film: 44% of patients had skin reaction, none of which progressed to moist desquamation (grade 1, 36%; grade 2a, 8%). - Comparator: 100% of patients had skin reaction, with 26% progressing to moist desquamation (grade 1, 28%, grade 2a, 46%, grade 2b, 18%, grade 3, 8%) Overall skin reaction severity reduced by 92% in favour of Mepitel Film (p<0.0001).
Lee et al, 2024 RCT (intra-patient) Australia	**Subjects:** 40 (age range 40-90 years) **Radiotherapy:** Chest wall / reconstructed breast ± regional lymph node irradiation **Setting:** Oncology centres (n=4)	**Safetac:** Mepitel Film **Comparator:** Silicone-based gel dressing (non-Safetac) Chest area divided into halves for randomisation to either Mepitel Film or gel dressing	Severity and duration of acute RISD (CTCAE) Patient preferences	Mean time-weighted average grade of RISD was 0.19 higher with the gel dressing (p<0.001). 40% of patients preferred Mepitel Film; 37.5% preferred the comparator dressing.

Abbreviations: AUC = area under curve; CAD = Canadian Dollars; CTCAE = Common Terminology Criteria for Adverse Events; EORTC = European Organisation for Research and Treatment of Cancer; HA = hyaluronic acid; ICER = incremental cost-effectiveness ratio; PREM = patient-reported experience measures; PROM = patient-reported outcome measure; QALY = quality-adjusted life year; RCT = randomised controlled trial; RISD = radiotherapy-induced skin damage; RISRAS = Radiation-induced Skin Reaction Assessment Scale; RTOG = Radiation Therapy Oncology Group; SSA = Skin Symptom Assessment; SSD = silver sulphadiazine

In New Zealand, Herst and colleagues undertook an RCT to evaluate the effect of Mepitel Film on skin reaction severity and the incidence of moist desquamation when used prophylactically in 78 **breast cancer** patients. Lateral and medial halves of the skin areas to be irradiated were randomised to either the film dressing or aqueous cream. Skin dose was measured using thermoluminescent dosimeters and skin reaction severity was assessed using RISRAS and RTOG scales. The RTOG data revealed that all of the skin areas that had aqueous cream applied developed some form of reaction (which progressed to moist desquamation in 26% patients), whereas reactions occurred in only 44% of the areas that had the film dressing applied (none of which progressed to moist desquamation). Likewise, the RISRAS data demonstrated an overall skin reaction severity reduction of 92% (p<0.0001) in favour of the film dressing (Herst et al, 2014).

The efficacy of Mepitel Film was also investigated in an RCT undertaken across multiple centres in Denmark involving 79 **breast cancer** patients receiving radiotherapy. Lateral and medial halves of the skin areas to be irradiated were randomised to either the film dressing or a regimen in accordance with Danish National Clinical Guidelines (comprising daily washing and the application of moisturising lotion and/or lotion with glucocorticoids for itching). A questionnaire was used to capture patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). Compared to the comparator regimen, the film dressing was associated with statistically significant reductions in pain severity (p<0.001), itching (p=0.005), burning sensation (p=0.005), oedema (p=0.017), and reduced sensitivity (p<0.001). Furthermore, 76% of patients indicated that they would have preferred to have had the film dressing applied to the entire irradiated area (p<0.001), with 85% of patients stating that they would have liked to have had the film dressing as a standard treatment option (p<0.001). While a significantly lower severity of RISD was observed in patients after mastectomy in the film dressing group (p=0.005), a blinded evaluation revealed no significant differences between the two groups at follow-up (Møller et al, 2018).

In 2021, a study was undertaken in Canada to assess the feasibility and efficacy of Mepitel Film for the prevention of RISD in 30 patients receiving external beam radiotherapy to the **breast** and **chest wall**. The primary outcome was RISD (graded using the CTCAE assessment tool). Outcomes were compared to previously published data relating to similar patients receiving standard prophylaxis for RISD. Two patients (6.7%) discontinued use of the film dressing before completing radiotherapy. No patients developed grade 3 or higher RISD. Five patients (17.9%) developed grade 2 RISD; three (10.7%) had moist desquamation and two (7.1%) had brisk erythema without moist desquamation. The authors concluded that the film dressing completely prevented grade 3 RISD, with the rates of moist desquamation and grade 2 RISD being lower than previously reported rates associated with aqueous cream (Yee et al, 2021).

However, unlike previous trials, the use of the film dressing did not achieve complete prevention of moist desquamation in the study reported by Yee and colleagues, indicating the need for further research to confirm the efficacy of the film dressing for RISD and to identify those patients likely to benefit the most from the dressing. Consequently, an RCT was undertaken across three oncology centres in Canada in patients who had undergone **lumpectomy (large breasts)** or **mastectomy** (irrespective of breast size). In total, 376 patients were recruited and randomised to receive either Mepitel Film or aqueous cream. In addition to using the CTCAE and RISRAS assessment tools, patients and clinicians rated the same parameters as those in the RISRAS tool using a Skin Symptom Assessment (SSA) scale. During and after radiotherapy, the film dressing group had significantly fewer patients with grade 2 or 3 RISD than those in the comparator group (odds ratio (OR): 0.20; p<0.0001). The total RISRAS scores were significantly lower in the film dressings group (p<0.001), as were the patient-assessed SSA scores for blistering/peeling, erythema, pigmentation and oedema (p≤0.03) and the clinician-assessed SSA scores for pain/soreness, blistering/peeling, erythema and pigmentation (p≤0.001) (Behroozian et al, 2023). A cost-effectiveness analysis of the data generated from this RCT was

subsequently undertaken. This involved the collation of direct and indirect cost data from two oncology centres, and the derivation of QoL utility values from mapping Dermatology Life Quality Index scores to the EQ-5D patient-reported outcomes instrument. Base case analysis demonstrated that Mepitel Film was cost-effective in preventing grade 2 or higher RISD as compared with the comparator with an incremental cost-effectiveness ratio (ICER) of CAD 3366 Canadian Dollars (CAD) per QALY gained. When indirect costs were included, Mepitel Film resulted in an ICER of CAD 2823 per QALY gained. The probabilistic sensitivity analysis confirmed that Mepitel Film demonstrates 100% probability of cost-effectiveness at a $50,000 per QALY threshold (Tse et al, 2026). As noted by Valcarenghi and colleague, the results of this trial are particularly interesting given that the recruited patients are representative of those at particularly high risk for RISD (Valcarenghi et al, 2025).

An RCT undertaken across two hospitals in Switzerland, involving patients with **breast cancer** compared Mepitel Film (n=75) with a regime comprising an aqueous-urea cream (applied at the beginning of radiotherapy) and either a silver sulphadiazine (SSD) or SSD with hyaluronic acid (HA) cream (applied at the onset of moist desquamation) (n=79). Moist desquamation (RTOG score ≥2) was observed in 9.5% of the film dressing group compared to 13.9% of the comparator group (p=0.393). Although no statistically significant difference was observed between the two groups in relation to the proportion of patients with moist desquamation, the time to appearance of RTOG ≥ 2 was significantly longer (p=0.035) and the skin recovery time was significantly shorter (p=0.027) in the film dressing group. Furthermore, the film dressing with Safetac was well tolerated by patients (Valcarenghi et al, 2025).

Also in 2025, a multicentre, intra-patient, RCT was conducted across 4 hospitals in Australia involving 40 patients undergoing post-mastectomy radiotherapy for **breast cancer**. Patients were randomly assigned to receive either a silicone-based gel dressing (non-Safetac) to one half of the irradiated chest area and Mepitel Film to the alternate half, comparing their efficacy in reducing the severity and duration of acute RISD. Both treatments were applied from the first day of radiotherapy until complete resolution of acute RISD. Patients had weekly assessments of dermatitis severity for a period of 10 weeks, or until complete resolution (whichever occurred sooner). Acute RISD severity was graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.0). The gel dressing did not meet the non-inferiority threshold compared with the film dressings in relation to the primary outcome. Indeed, statistical significance was found in terms of acute RISD severity between the two dressings (mean time-weighted average RISD grade was 0.19 higher in the gel dressing group, p<0.001); as such, the authors concluded that the gel dressing should be considered inferior, compared to the film dressing (Lee et al, 2025).

Film dressings in the prevention and management of radiotherapy-induced skin damage in head and neck cancer patients

An RCT was conducted to investigate the feasibility of using Mepitel Film (for both prophylaxis and management of RISD) in **head and neck cancer** patients (n=33) undergoing radiotherapy or radio(chemo) therapy (two patient cohorts were included, one from New Zealand and one from China). An area of the neck receiving a homogenous radiation dose of >35 Gy was divided into two equal halves; one half was randomised to film dressings, the other to moisturising creams. Skin reaction severity was measured using RISRAS and expanded RTOG criteria. Results were pooled for prophylactic and management protocols, given similarities found in terms of the protective effect of the film dressing. Skin reaction severity, as measured using the extended RTOG grading system and the combined RISRAS, showed a decrease in skin reaction severity and moist desquamation rates. However, while the film dressing did not affect head movement, it was reported that the dressing did not adhere well to the skin, particularly in males with heavy beard stubble, and caused itchiness, particularly in the Chinese patients (Wooding et al, 2018).

Given the positive results, particularly in the Chinese cohort of patients without heavy stubble, the same research group conducted a second RCT, for which datasets from 28 Chinese patients were added to those of the 11 Chinese patients included in the feasibility study to determine whether or not Mepitel Film is superior to the moisturising creams in managing RISD, including moist desquamation, in **head and neck cancer** patients. Skin reaction severity was measured using RISRAS and expanded RTOG grades. While skin dose underneath the film dressing and the moisturising creams were similar, skin reaction severity (using the combined RISRAS) underneath the film dressings was decreased by 30% (p<0.001) and moist desquamation rates were reduced by 41% (p<0.001). Importantly, 80% of patients preferred the film dressing over the moisturising cream. However, there were some reports of poor adherence and patient discomfort with the film dressing during hot weather and showering, and itching skin underneath it. Overall, the authors concluded that when used prophylactically, the film dressing was superior to the moisturising creams in reducing the severity of acute RISD and incidence of moist desquamation in this patient cohort (Yan et al, 2020).

Foam dressings in the management of RISD

Several studies have explored the role of Mepilex Lite in the management of RISD. These are summarised below and in **Table 4.**

Table 4. Management of radiotherapy-induced skin damage – foam dressings - key studies

Reference / Study type / Country	Number of subjects / Wound types / Setting	Dressings evaluated	Main outcome measures	Main results
Zhong et al, 2013 RCT China	**Subjects:** 88 (age range not specified) **Radiotherapy:** Head / neck with concurrent chemoradiotherapy **Setting:** Oncology centre	**Safetac:** Mepilex Lite (n=43 patients) **Comparator:** Usual care (n=45 patients)	Time to healing Pain (measured using VAS 0-10) Neck mobility, sleep problems and appearance disturbance (measured using 10-pont Likert scale – higher scores indicative of more distress)	Shorter median time to healing in the Mepilex Lite group (p=0.009): - Mepilex Lite: 16 - Comparator: 23 Lower mean pain scores in the Mepilex Lite group (p=0.02): - Mepilex Lite: 5.31 - Comparator: 6.89 Lower mean sleep problem score in the Mepilex Lite group (p=0.005): - Mepilex Lite: 4.38 - Comparator: 7.23 No statistically significant differences between groups in neck mobility and appearance disturbance.
Paterson et al, 2012 RCT (intra-patient) New Zealand	**Subjects:** 74 (age range 29-84 years) **Radiotherapy:** Chest wall **Setting:** Oncology centres (n=4)	**Safetac:** Mepilex Lite **Comparator:** Aqueous cream Chest area divided into halves for randomisation to either Mepitel Film or aqueous cream	RISD severity (RISRAS) Occurrence of moist desquamation Patient preferences	41% reduction in overall RISD severity with Mepilex Lite, relative to comparator (p<0.001). Moist desquamation incidence: - Mepilex Lite: 15% - Comparator: 19% 49% reduction in average moist desquamation (RISRAS) score (p=0.043): - Mepilex Lite: 0.18 - Comparator: 0.37 28% reduction in length of time of moist desquamation: - Mepilex Lite: 25 weeks - Comparator: 18 weeks Most patients preferred Mepilex Lite (easy to use, comfortable to wear). Dressing outperformed comparator in terms of pain/discomfort, itchiness, burning and effect on daily life.

Abbreviations: RCT = randomised controlled trial; RISD = radiotherapy-induced skin damage; RISRAS = Radiation-induced Skin Reaction Assessment Scale; VAS 0-10 = visual analogue scale from 0 (no pain) to 10 (worst pain imaginable)

In 2012, an intra-patient, multicentre RCT was conducted to evaluate the effect of Mepilex Lite dressings on the overall severity of chest wall RISD, the incidence of moist desquamation, the time to moist desquamation, and time to healing in 74 **post-mastectomy** patients. The intervention started from the time erythema first appeared (generally about 10-14 days after the first fraction). The dressings with Safetac were allocated to either the superior/left or inferior/right areas where erythema was present; the other continued to have aqueous cream applied (control area). Skin reactions were measured using RISRAS. Fewer areas underneath the dressings with Safetac developed moist desquamation than in the areas that had aqueous cream applied (difference not statistically significant). However, compared to the control group, a 41% reduction in overall severity of RISD was achieved in the dressings group (p<0.001). Furthermore, the average moist desquamation score was reduced by 49% (p=0.043). The total number of weeks of moist desquamation in the areas underneath the dressings was found to be 28% lower compared with that of the control areas. Most patients preferred the dressings to the aqueous cream, finding them easy to use and very comfortable to wear. Furthermore, the dressings outperformed aqueous cream with regards to pain/discomfort, itchiness, burning and effect on daily life (Paterson et al, 2012).

Diggelmann and colleagues investigated the efficacy of Mepilex Lite dressing in reducing radiation-induced erythema in 24 women (34 erythematous areas) with **breast cancer**. The areas of erythema were randomly divided into two halves; one half was covered with the dressing and the other half had aqueous cream applied. The extent of erythema was measured using the RISRAS scale. The dressings with Safetac significantly reduced the severity of radiation-induced erythema when compared with aqueous cream (p=0.001). There were eight instances of skin breakdown reaching dry desquamation

in the areas that had aqueous cream applied (24%), compared with five (15%) of the skin areas that had dressings applied. The majority (17/24) of patients preferred the dressings over the cream; patients indicated that the dressings increased comfort levels, decreased the amount of pain experienced and allowed them to wear normal clothing. It was also noted by patients that the dressings were soothing and provided pain relief and relief from friction (Diggelmann et al, 2010).

In a small two-centre study, patient comfort and overall experience when using Mepilex Lite in the management of dry and moist desquamation during radiotherapy were evaluated in 16 patients undergoing radiotherapy to the **head** and **neck** or **breast**, and who had a RTOG score of 3 plus 1 symptom measured via the RISRAS. Most patients found the dressing comfortable to wear and remove, and in many cases it had a positive impact on daily living. Benefits reported included reduction of friction (e.g. from clothes), minimisation of pain during dressing changes, ease of lifting and readjustment without loss of adherent properties, a cooling and soothing effect on the skin, and improved sleep pattern (MacBride et al, 2008).

The effectiveness of Mepilex Lite dressings in the management of RISD (resulting from curative-intent radiotherapy) in **nasopharyngeal carcinoma** patients (n=88) was investigated in an RCT conducted in China. Patients were randomised to either dressings with Safetac (n=43) or the standard care provided at the study centre (n=45). A significantly shorter median time to RISD healing was observed in the dressings group (16 days) than in the standard care group (23 days) (p=0.009). No statistically significant differences were found between the two groups in regards to neck mobility and appearance disturbance. However, a significant improvement in patients' sleep (p=0.005) and a significant reduction in pain (p=0.02) in favour of the dressing group were observed (Zhong et al, 2013).

A case study has been reported in which the exudate transfer dressing, Mepilex Transfer, was used in the management of RISD (**moist desquamation**). When applied to the severe RISD, the dressing provided good skin protection, was easy to use and remove, and exhibited good conformability and adaptability on difficult-to-dress areas. The patient also found the dressing to be comfortable to wear and experienced a reduction in pain severity (Lemos et al, 2016).

Wound contact layers in the prevention of radiotherapy-induced skin damage

In a pilot study undertaken in Germany, Mepitel was used on 21 patients receiving radiotherapy, seven with intact portal skin and 14 in whom the portal included an epitheliolysis and a skin ulcer. The portals were located on the **neck, breast, pelvis, groin, thorax, nose, forehead, head, spine** and **thigh**. There were no reactions to the dressing on non-irradiated skin, no additional skin irritation in the irradiated regions, and no injury to new epithelium at dressing changes. The ulcers covered with the wound contact layer re-epithelialised quickly. Furthermore, the tolerance of the wound contact layer was good in all patients (Adamietz et al, 1995).

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