Supportive Care in Cancer (2023) 31:713
https://doi.org/10.1007/s00520-023-08190-8

REVIEW

StrataXRT for the prevention and treatment of radiation dermatitis: a critical review

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Received: 28 March 2023 / Accepted: 15 November 2023 / Published online: 21 November 2023

Abstract

Purpose The primary objective is to systematically review primary studies, such as randomized control trials (RCTs), feasibility, exploratory, and case studies; and the secondary objective is to evaluate all secondary articles, such as reviews, guidelines, and editorials, relevant to the use of StrataXRT for the prevention and/or management of radiation dermatitis (RD) in cancer patients.

Methods A literature search was conducted up to February 26, 2023, for articles investigating the use of StrataXRT for the prevention and treatment of RD, in the following databases: Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Google Scholar. The keywords "StrataXRT", "dermatitis", "radiotherapy", and "radiation" were used to identify relevant articles.

Results Twenty-seven articles from 2018 to 2022 were identified to fulfill the inclusion criteria of this review, of which nine are primary studies and 18 are secondary papers. Significant heterogeneity was observed in the current literature studying the effects of StrataXRT, making it difficult to make cross-trial comparisons. There is a suggestion of the efficacy of StrataXRT in the prevention and treatment of RD.

Conclusion The findings of this review recommend further adequately powered RCTs with robust methodology including patient and clinician assessments to determine the efficacy of StrataXRT in preventing and treating RD. This is essential to improve the quality of life of patients and identify which groups of patients would benefit most from StrataXRT.

Keywords Radiation dermatitis · Skin toxicity · Patient-reported outcome · StrataXRT · Review

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Introduction

Radiation therapy (RT) is commonly used to treat many types of cancer. Despite the benefits of RT, many patients experience adverse events resulting from the treatment [1]. One of the most common symptoms is radiation dermatitis (RD), which occurs in up to 95% of patients undergoing RT [1]. RT induces DNA damage preferentially in cancerous cells, but this ionizing radiation can also cause dividing non-cancerous basal stem cell death in the epidermis by releasing histamine-like substances and damaging DNA [2]. This continuous damage leads to the thinning of the skin and can ultimately result in dry/moist desquamation [2]. Dry desquamation presents as pruritus, scaling, the flaking of dry skin, and moist desquamation as tender and moist skin with leaking serous fluid [1]. RD developing within 90 days of the start of treatment is referred to as acute RD and levels of severity range from acute erythema to dry and moist desquamation [1]. Severe skin reactions during RT can necessitate interruptions or early termination of treatments, highlighting the importance of managing RD to improve RT outcomes and effectiveness [2]. Various tools are used to assess RD outcome severity, such as the Common Terminology Criteria for Adverse Events (CTCAE), the Radiation Therapy Oncology Group (RTOG), and the World Health Organization criteria [3].

No international standard of care for RD has been established. In Canada, the Canadian Skin Management in Oncology group suggests utilizing cleansers and moisturizers to support skin hydration which may reduce cutaneous toxicities [4]. In the United Kingdom, the Society and College of Radiographers stated that there was not enough strong evidence to support or refute the use of any topical product to treat RD, and they identified washing the skin, moisturizers, steroid-based creams, photo biomodulation therapy, oral enzymes, topical emollients, and wound dressings as potential prophylactic methods [5].

Meanwhile, evidence in support of silicone-based products, including Mepitel film and StrataXRT, has been growing since 2004 through a series of clinical trials. The Mepitel film is a silicone-based polyurethane barrier film [6]. Several randomized controlled trials (RCTs) and non-RCTs have been conducted to clarify the efficacy of the prevention and treatment of radiation dermatitis in patients receiving RT for breast or head and neck cancer [7–9]. Another silicone-based wound dressing called StrataXRT was developed for the prevention and treatment of RD after Mepitel film. StrataXRT is made of polydimethylsiloxanes, siloxanes, and alkyl methyl silicones, which forms a protective bacteriostatic layer that reduces the risk of contact dermatitis and protects the skin from irritants and microbes [10]. StrataXRT also promotes oxygen exchange, and hydrates the irradiated skin, subsequently minimizing trans-epidermal water loss [10]. This is believed to create a moist wound healing environment and reduces the severity of common adverse symptoms of RD, like dry/moist desquamation, by promoting reepithelization [10] Due to the flexible nature of StrataXRT, it can be applied to regions like the supraclavicular area, high mobility joints, high friction areas/regions such as the axilla, genitals, and hairy areas of skin [11]. StrataXRT can be applied by patients without healthcare provider (HCP assistance), thus, saving time and hospital resources.

To evaluate the efficacy of StrataXRT for the prevention and/or management of RD, we performed a systematic review on all the primary studies such as RCTs, feasibility studies, exploratory studies, and case studies, relevant to the use of StrataXRT to prevent and/or manage radiation dermatitis (RD) in cancer patients as the primary objective. All secondary articles such as review, guidelines, and editorials, relevant to the use of StrataXRT for the prevention and/or management of RD in cancer patients were reviewed as a secondary objective.

Methods

This systematic review was prepared as guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12].

Search strategy

A literature search was conducted up to February 26, 2023, to identify articles investigating the use of StrataXRT for the prevention and treatment of RD in the following databases: Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Google Scholar. The keywords "StrataXRT", "dermatitis", "radiotherapy", and "radiation" were used to identify relevant articles (Appendix 1). The search results were divided based on the primary and secondary objectives. The search was limited to human studies with adult populations.

Article selection

Results were screened using Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia (available at www.covidence.org) [13]. It is a web-based collaboration software platform that streamlines the production of systematic and other literature reviews [13]. Two authors independently conducted title/abstract screening and full text screening (MG and SA). The complete data from included studies were then extracted

independently by two authors (MG and SA). Conflicts were resolved by discussion between the authors or consultation with a third author (SS).

Primary research studies were included in the systematic review if they specifically assessed the use of StrataXRT for treatment and/or prevention of RD and investigated StrataXRT alone or compared it to another intervention. Additionally, relevant studies of all other designs were included in the critical review. Studies were excluded if they were not written in English or did not evaluate StrataXRT for the prevention/treatment of RD.

Data collection and analysis

The following data were extracted: title, year of publication, first author, country of study, aim of study, assessment methods, study design, total participants and/or studies, participants included in the analysis, strengths/weaknesses of the studies, and their main findings.

Results

Study selection

Figure 1 presents a flowchart of the study inclusion process. We identified 109 studies from the four databases. After removing 43 duplicates, 66 titles and abstracts were assessed. Fourteen records did not meet the inclusion criteria and were excluded. The full texts of 52 citations were examined in detail. Twenty-seven studies fulfilled the inclusion criteria. There were nine primary studies identified in the systematic review and 18 secondary articles. The primary studies were conducted in various countries including Australia, New Zealand, Spain, Korea, Iran, and the United States of America. Two RCTs and a feasibility study reported on RT for head and neck cancer [11, 14, 15], three RCTs studied RT for breast cancer [16–18], and the remaining feasibility, case, and exploratory studies looked at multiple radiation sites [19–21]. Table 1 outlines the characteristics of primary research studies included in the systematic

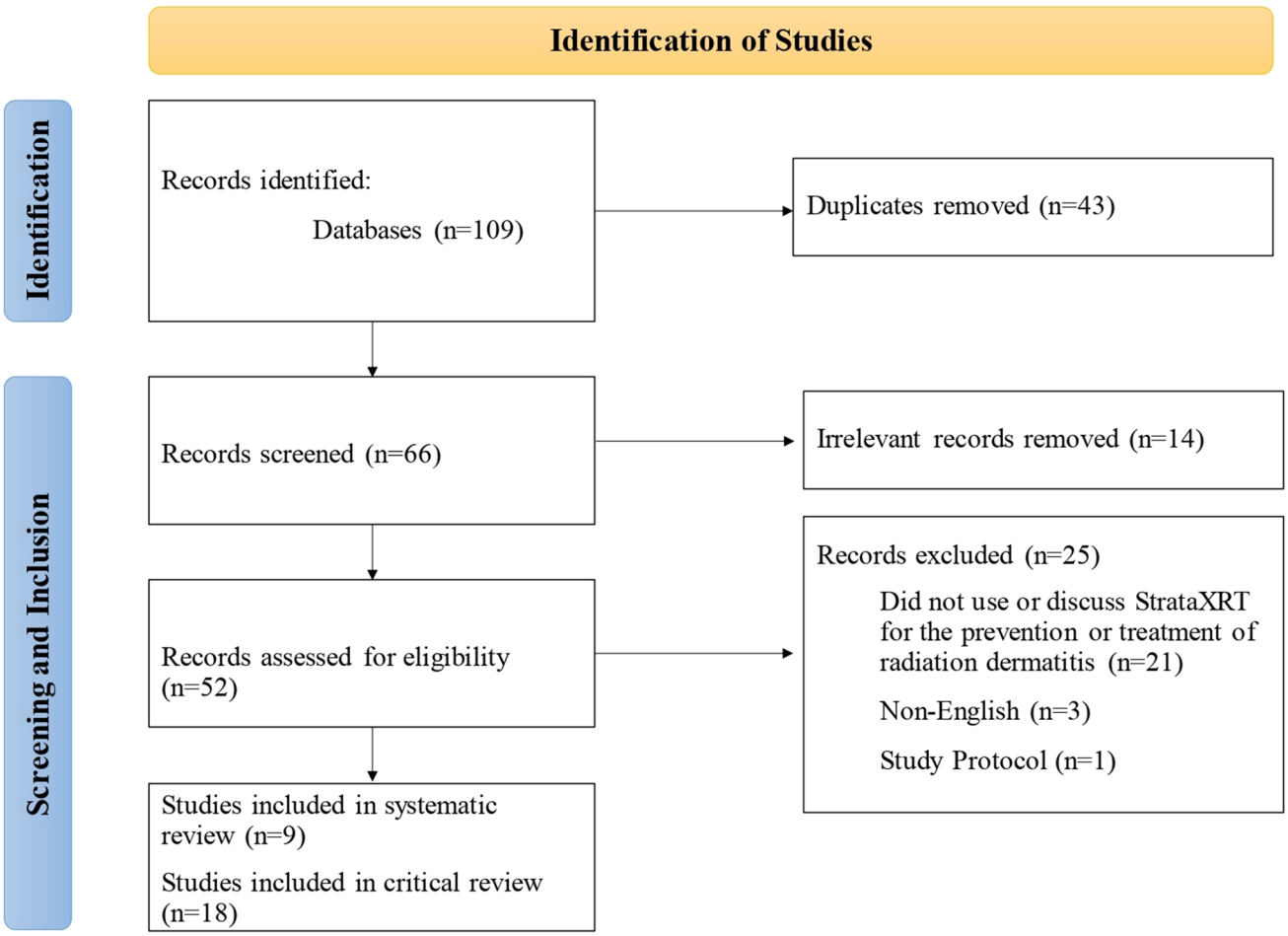

Fig. 1 PRISMA Flow Diagram of Study Selection

Table 1 Study Characteristics for Primary Studies

First Author (Year)	Study Type	Country	Inclusion Criteria	Mean Age (Range)	Sample Size Enrolled; Included in Analysis	Cancer stage	Inter/Intra-patient Intervention Comparison	Interventions Used, Frequency, and Duration	Scoring Systems	Strengths	Limitations
O'Dell and Kearney, 2018	Feasibility study	New Zealand	Patients with head and neck cancer receiving RT	NR	20; 20	Non-metastatic stages	Inter-patient	StrataXRT group (prospective) (n = 10); control group (retrospective) (n = 10), twice daily from first RT to one-week post RT	Patient component of RISRAS RTOG	Consistency in population characteristics between StrataXRT and control group Scoring undertaken by single assessor; consistent assessments Assessed patient satisfaction Conducted cost-analysis	Only followed to one-week post-RT RISRAS only completed by patient who used StrataXRT Used retrospective data for control group
Villandiego and Aramberri, 2018	Case Series	Spain	Patient undergoing RT that developed significant erythema during treatment (Non-specific cancer – tongue, rectal, and submaxillary gland),	StrataXRT: 57.0 years (50–69)	5; 5	NR	N/A	StrataXRT only, began use if patient developed grade2 + erythema, purities, and/or desquamation, until skin appears healed	Interviews, questionnaires, observation by nurses	Investigated different RT sites which allowed to investigate the gel's adaption for all surfaces Investigated StrataXRT for treatment of RD	No control group or randomization Combined cancer therapy—cannot assess chemo-related variables Did not provide questionnaires/methods of skin assessment used Did not assess patient-reported outcomes/experience or QoL

Table 1 (continued)

First Author (Year)	Study Type	Country	Inclusion Criteria	Mean Age (Range)	Sample Size Enrolled; Included in Analysis	Cancer stage	Inter/Intra-patient Intervention Comparison	Interventions Used, Frequency, and Duration	Scoring Systems	Strengths	Limitations
Quilis et al., 2018	Exploratory study	Spain	Patients undergoing RT for different cancer types developing RD (RTOG score of 2.5 ± 0.5))	StrataXRT: 55.7 years (35–75)	54; 28	NR	N/A	StrataXRT only, began using when RTOG score of 2.5 (± 0.5) during RT, until skin appears healed	Patient and research components of RISRAS RTOG HCP-assessed 5-item Likert scale Patient-reported product evaluation sheet	Used standardized questionnaires Assessed patient experience	Large number of withdrawals from statistical analysis due to lack of adherence to protocol Unblinded skin assessment by HCP No control groups
Chan et al., 2019	RCT	Australia	Patients with head and neck cancer receiving radical RT (≥ 50 Gy) with or without chemotherapy or biotherapy	StrataXRT: 64.0 years Control agent: 63.6 years	197; 172	Non-metastatic stages	Inter-patient	StrataXRT group (n = 100); moisturizer group (n = 97), twice daily, from first RT to four weeks post-RT	CTCAE Skindex-16 BPI Itching (0–10)	Random allocation to control agent or StrataXRT Blinded skin assessments conducted weekly	Patients and clinicians were unblinded, only outcome assessor blinded – no effect on the primary outcome
Chao et al., 2019	RCT	Australia	Post-mastectomy breast cancer patients undergoing chest wall with or without nodal irradiation RT	NR	44; 40	Non-metastatic stages	Intra-patient	Lateral/medial halves of radiation field were randomized to Mepitel Film or StrataXRT, length of application NR	CTCAE	Randomization Used standardized assessment tools	No QOL Assessment No patient-reported outcomes Intrapatient control

Table 1 (continued)

First Author (Year)	Study Type	Country	Inclusion Criteria	Mean Age (Range)	Sample Size Enrolled; Included in Analysis	Cancer stage	Inter/Intra-patient Intervention Comparison	Interventions Used, Frequency, and Duration	Scoring Systems	Strengths	Limitations
Ahn et al., 2020	RCT	Korea	Women with breast cancer receiving RT post-lumpectomy	StrataXRT: 46 years (40–56) Control agent: 49 years (29–60)	56; 49	Non-metastatic stages	Inter-patient	StrataXRT group (n = 21); moisturizer group (n = 28), twice daily, from first RT to four weeks post-RT	EI, MI and TEWL measured using reflectance spectrophotometer CSSP RTOG CTCAE Patient-reported symptoms assessed using a five-point scale questionnaire	Random allocation to control agent or StrataXRT Physiological skin parameters and skin condition assessed by a blinded researcher StrataXRT group and control group were well-balanced in clinical characteristics, no differences in baseline assessments Assessed patient-reported outcomes	Did not assess effect on QoL Used physiological skin parameters, non-standardized RD assessment tool

Table 1 (continued)

First Author (Year)	Study Type	Country	Inclusion Criteria	Mean Age (Range)	Sample Size Enrolled; Included in Analysis	Cancer stage	Inter/Intra-patient Intervention Comparison	Interventions Used, Frequency, and Duration	Scoring Systems	Strengths	Limitations
Rutten et al., 2021	Feasibility Study	New Zealand	Head and neck cancer patients undergoing RT	StrataXRT: 63.9 years (88–49) Control agent: 66.4 years (90–24)	55; 55	Various stages	Inter-patient	StrataXRT (n = 25); retrospective control group (n = 30), twice daily from first RT until 2-week post-RT	CTCAE RISRAS Product usage questionnaire	Assessed both HCP and patient perspective	No skin dose measurements were taken to confirm the skin DVH data Used retrospective data for control group No randomized CTCAE scores only had 41% of scores recorded
Omidvari et al., 2022	RCT	Iran	Patients with breast cancer receiving RT post-lumpectomy	StrataXRT: 45.08 years	100; 100	Non-metastatic stages	Inter-patient	StrataXRT (n = 50); moisturizer (n = 50), twice daily during RT	RTOG RD measured through transparent paper per square centimeter	Random allocation to control agent or StrataXRT Quantitative and qualitative skin assessment methods	Unblinded skin assessments Did not assess patient-reported outcomes/experience or QoL
Bryant et al., 2019	Feasibility Study	United States of America	Patients with head and neck, breast, pelvis, skin, or lung cancer treated with curative intent in the head/neck region	61	56; 56	NR	N/A	StrataXRT group only, used StrataXRT at least twice daily after first RT and continue until RD resolved	NR		No control group or control data mentioned No randomization or stratification No patient-reported outcomes Assessment tool for HCPs not reported

RCT = randomized controlled trial; RT = radiotherapy; RTOG = Radiation Therapy Oncology Group; RD = radiation dermatitis; CSSP = Catterall skin scoring profile; CTCAE = Common Terminology Criteria of Adverse Events; EI = Erythema Index; MI = Melanin Index; TEWL = Trans-epidermal water loss (g/h/m2); BPI = Brief Pain Inventory; RISRAS = Radiation Induced Skin Reaction Assessment Scale; HCP = health care provider; ICER = Incremental cost-effectiveness ratio; DVH = Dose-Volume Histogram; NR = not reported

Table 2 Outcomes Assessed for Primary Studies

First Author (Year)	HCP-Assessed RD	Patient-Assessed RD	Patient Experience
O'Dell and Kearney, 2018	Moist desquamation Small difference in incidences: StrataXRT group ($n=10$) Control group ($n=8$) StrataXRT: longer time to onset and faster recovery	Score were generally low for each section such as pain, itching, burning and effect on daily activities	3/6 (50%) scored a 7 (completely satisfied) 2/6 (30%) scored a 6 (mostly satisfied) 1/6 (17%) scored below a 4 (unsatisfied) 9/10 (90%) said StrataXRT was easy to apply and was soothing
Villandiego and Aramberri, 2018	Assessed via observation by nurses	N/A	N/A
Quilis et al., 2018	Increased hydration of the skin during radiation by 26.0% ($p=0.021$) Decreased skin inflammation by 28.9% ($p=0.011$) Decrease in erythema by 20.6% ($p=0.015$) Overall RISRAS score decreased by 16.9% by the end of RT ($p=0.004$) No significant differences in size of open wound area, size of bleeding wound area, or size of exudative area	Decrease in pain by 20.5% ($p=0.005$) Decreased itchiness by 22.2% ($p=0.002$) Decreased burning sensation by 24.7% ($p=0.003$)	Ease of use rated "excellent" by 50% of respondents (n=8) Comfort rated "very good" by 44% (n=7) General perception: "excellent" 44% (n=7) and 38% (n=6) as "very good."
Chan et al., 2019	StrataXRT: 12% reduced risk of grade 2 skin toxicity (RRR=0.876, 95% CI: 0.778–0.987, $p=0.031$) 36% reduced risk of grade 3 skin toxicity (RRR=0.648, 95% CI: 0.442–0.947, $p=0.025$) Onset of RD: 75% of patients 6 weeks (StrataXRT), 5 weeks (control) Risk of developing grade 3 RD during treatment: 49.4% for StrataXRT group Incidence of grade 3 skin toxicity: 28% (StrataXRT) vs. 45% (control) group	BPI and numeric analogue scale for itching severity (0–10, increasing severity) No statistically significant difference between groups	No statistically significance difference in Skindex scores between groups
Chao et al., 2019	StrataXRT halves: Grade 1=30%, Grade 2=70% Mepitel Film halves: Grade 0=5%, Grade 1=42.5%, Grade 2=50%, Grade 3=2.5% Incidence of moist desquamation in StrataXRT and Mepitel Film groups were 12.5% and 20% respectively ($p=0.099$)	N/A	N/A
Ahn et al. 2020	No significant differences between StrataXRT and the control group No incidences of moist desquamation Significant difference in peak EI higher in control group than StrataXRT ($p=0.008$) Significant difference in peak MI higher in control group than StrataXRT ($p=0.015$) Moderate correlation of EI and MI with clinician-assessed visual rating scales Strong correlation between EI and CSSP	No statistically significant differences between StrataXRT group and control group	N/A

Table 2 (continued)

First Author (Year)	HCP-Assessed RD	Patient-Assessed RD	Patient Experience
Rutten et al., 2021	Similar percentages of RD scores per patient in grades 0–2 Grade 3 RD: 20% (control), 9% (StrataXRT) Mean maximum RISRAS score: 1.6 (SD = 1.3), StrataXRT: 1.1 (SD = 1.0)	No statistically significant difference in RISRAS scores between the control and study groups	Gel easy to use and comfortable on the skin Some reports of discomfort due to stickiness of the gel, and difficulty applying it once pain/tenderness begun during treatment
Omidvari et al., 2022	Until week 4 following RT completion, the incidence of RD grades 1–4 were significantly less in the StrataXRT group ($p < 0.05$) Incidence of moist desquamation in StrataXRT and supportive care groups were 6% and 50% respectively	N/A	N/A
Bryant et al., 2019	Acute grade 2 + : 58.9% Acute 3 + RD: 10.7% Acute grade 2 + RD based on anatomic site: head and neck (69.0%), breast (60.0%), pelvis (37.5%), skin (28.6%), and lung (10.0%) Acute grade 3 + RD based on anatomic site: head and neck (13.8%), breast (10%), pelvis (0%), skin (14.3%), and lung (0%)	NR	NR

RT = radiotherapy; RD = radiation dermatitis; CSSP = Catterall skin scoring profile; RTOG = Radiation Therapy Oncology Group; CTCAE = Common Terminology Criteria for Adverse Events; EI = erythema index; MI = melanin index; BPI = Brief Pain Inventory; HCP = health care provider; RISRAS = Radiation-Induced Skin Reaction Assessment Scale; NR = not reported; N/A = not applicable

Table 3 Study Characteristics and Results for Reviews, Meta-Analyses, Guidelines, and Economic Evaluations

First Author (Year)	Study Type	Inclusion Criteria or Study Objective	Papers Included	Total No. of Participants	Strengths	Limitations	Conclusions
Agbejule et al., 2021	Guideline	To update a previous systematic review on prevention and management of radiation-induced skin reactions. To develop evidence-based clinical guidelines for use of topical interventions in the prevention and management of RD	36	N/A	ROB conducted; majority of studies had low risk of bias (including Chan et al.)		Recommends against topical interventions due to insufficient evidence and aloe vera. Moderate confidence for the use of betamethasone 17-valerate cream, and some confidence for silicone-based film forming gel dressing (intermediate quality of evidence) and mometasone furoate cream
Ginex et al., 2020	Systematic review and meta-analysis	RCTs or nonrandomized studies with a comparison group, management or treatment of RD, an adult population, and any cancer site	22; 8 relating to the use of barrier films	3127	Compared variety of RD prevention/treating methods ROB assessment conducted Quality assessments of included studies performed using AMSTAR-2 Thorough analysis of each study with evidence-guided recommendations Graded evidence strength	Grey literature eliminated Research provides low to moderate evidence Systematic review does not specifically study StrataXRT; combines StrataXRT with other barrier films	StrataXRT, amongst other topical steroids and dressings, shows a benefit in minimizing the development of RD and moist desquamation while lowering rates of patient-reported symptoms
Gosselin et al., 2020	Guideline	Used systematic review and meta-analysis conducted by Ginex et al. to guide a panels' guideline development	See Ginex et al., 2020	See Ginex et al., 2020	Discusses harms and benefits of various interventions Provides recommendations for clinical practice Discusses strength of recommendations	Systematic review does not specifically study StrataXRT; combines StrataXRT with other dressings	Panel acknowledged the evidence in support of barrier films, including StrataXRT Panel issued a conditional recommendation; suggest the potential use of semi-permeable dressings for the prevention of RD, in addition to the use of standard care

Table 3 (continued)

First Author (Year)	Study Type	Inclusion Criteria or Study Objective	Papers Included	Total No. of Participants	Strengths	Limitations	Conclusions
Iacovelli et al., 2020	Review	Studies investigating topical methods of RD prevention and treatment	34	NR	Provides clinical recommendations on managing RD	No comparisons between methods No bias or accuracy assessments of studies No specific assessment or discussion of when specific interventions may be beneficial	Silicone-based agents, including StrataXRT, are promising products for the promotion of wound healing Potential practical issues, including difficulties with adherence to the skin in certain areas
Shi et al., 2020	Guideline	Studies discussing various types of wound dressings for different wounds	NR	NR	Provides recommendations for clinical practice and research	Broad focus on different types of wounds; limited discussion on RD No comparison between various methods of RD prevention and treatment Does not incorporate patient perspective Does not provide an analysis on the strength of included papers	Authors report a lack of evidence based RCTs comparing different types of dressings for RD, and thus cannot make a conclusion regarding their efficacy
Probst et al., 2020	Systematic review	English RCTs, systematic reviews, nonrandomized trials, and case series that assess the use of a topical agent/dressing/intervention for prevention of RD	33	NR	Included grey literature, including Index to Theses and conference papers RCT quality evaluated using ROB tool Non-randomized study quality evaluated using ROBINS-I tool Systematic review quality evaluated using the Scottish Intercollegiate Guidelines Network checklist for systematic reviews,	Limited comparisons across studies Very few studies included had assessment of inter and intra-rater reliability of HCP assessments	Studies that assess barrier films and dressings are not significant enough for recommendations to be made; limitations in some study designs

Table 3 (continued)

First Author (Year)	Study Type	Inclusion Criteria or Study Objective	Papers Included	Total No. of Participants	Strengths	Limitations	Conclusions
Solanki et al., 2021	Guideline	N/A	N/A	N/A	Provide recommendations and observations regarding the use of StrataXRT Incorporate experts' opinions	Vague discussion on StrataXRT and treatment of RD Nodiscussion/comparison of RD treatment and prevention methods	The authors have seen significant reductions in erythema in patients using StrataXRT The authors currently recommend twice daily use of this topical gel
Kao et al., 2022	Meta-analysis	RCTs investigating the topical prevention of RD in head and neck cancer patients; human studies; studies written in English	14	1304	ROB tool used to evaluate RCT quality ROB individually assessed by two authors Funnel plot and Egger's test used to evaluate publication bias	No comparison of standard care between studies Some studies determined to have small sample sizes Indirect comparisons between studies	StrataXRT was not found to be significantly better compared to other standards of care. Olive oil was the only effective topical regime identified
Burke et al., 2022	Systematic review	Studies with cancer patients treated with external beam photon, proton, or electron bean RT, involving topicals, barriers or deodorant use guidance	33	NR	Provided specific, clinically relevant recommendations Presented both clinician and patient outcomes Assessed bias of each study and evaluated risk as either low, moderate, or high	Non comprehensive review; excludes conference abstracts and case studies Systematic review does not specifically study StrataXRT; combines StrataXRT with other barrier films	Insufficient evidence to support the use of barrier films, including StrataXRT, for the prevention of RD
Haesler et al., 2022	Evidence-based Summary	To summarize trials investigating RD prevention and/or treatment, and wound dressings/barrier films	5	NR	Conduced separate analyses for treatment- versus prevention-focused trials Provided considerations for use; clinically applicable Graded evidence levels and took grades into consideration during analysis	No reporting of exclusion/inclusion criteria, or population/study types considered Limited body of evidence/works	Some evidence to support use of StrataXRT to delay onset of severe RD, and promote faster healing from RD; evidence is weak

Table 3 (continued)

First Author (Year)	Study Type	Inclusion Criteria or Study Objective	Papers Included	Total No. of Participants	Strengths	Limitations	Conclusions
Zasadziński et al., 2022	Literature Review	RCTs and cohort studies investigating the use of various types of dressings for the prophylaxis and treatment of RD	35	NR	Incorporates patient-reported outcomes in review Comprehensive discussion of different dressing types available for management of preventing RD and their efficacy Provide recommendations of when dressings should be used, and type of dressing to be used depending on RT dose and progression	Despite the discussion and analysis of different dressing types, StrataXRT grouped with other products as "hydrogels"	Hydrogel dressings do not seem to be effective for the treatment of severe acute RD
Kiprian et al., 2022	Review	NR	NR	NR	Investigated a variety of novel RD prevention and treatment methods	No comparisons made between studies or products No bias assessment conducted No recommendations provided for novel approaches to RD management or treatment	Authors conclude that StrataXRT is promising for RD prevention
Rose, 2020	Editorial	To report the past and current use of silicone-based films/gels in preventing and managing RD	N/A	N/A			The advent of silicone-based dressings, film, and gels is potentially one of the most important interventions currently being introduced

Table 3 (continued)

First Author (Year)	Study Type	Inclusion Criteria or Study Objective	Papers Included	Total No. of Participants	Strengths	Limitations	Conclusions
Bailey et al., 2021	Practice consensus statement	To provide recommendations on various interventions for treating RD	N/A	N/A	Based on majority opinion of the Head and Neck Radiation Oncology experts at the University of Texas MD Anderson Cancer Center	Recommendations are for MD Anderson's specific patient population	Recommends for prophylaxis of RD: cream emollients and/or silicone gel such as StrataXRT or Scar Away, and topical steroids such as triamcinolone 0.1% cream and mometasone furoate 0.1% cream. Using film forming silicone gel for 3–6 months after finishing radiation therapy may help reduce pigment changes. It is noted that StrataXRT is preferred due to available published data
Tenorio et al., 2022	Review	To serve as a RD management guide	N/A	N/A	A panel of opinion leaders of the Mexican Society of Radiotherapy (SOMERA) took part in a study of oncologic practice in Mexico	Does not directly assess StrataXRT or review the existing literature studying StrataXRT	Recommends the use of dermo cosmetics/medical device in prevention and in treatment of RD grades 1–2. As for grade 3, they recommend individualizing each case and dermatologist evaluates. Topical steroids should be used when there is skin itching or pain. Encourages consideration of new approaches like photobiomodulation therapy and different barrier films/dressings such as StrataXRT

Table 3 (continued)

First Author (Year)	Study Type	Inclusion Criteria or Study Objective	Papers Included	Total No. of Participants	Strengths	Limitations	Conclusions
Wolf et al., 2022	Literature Review	To discuss the pathogenesis, clinical manifestations, and treatment of RD	NR	N/A	Assesses StrataXRT individually as a silicone-based gel dressing	Review methodology was not reported	There is limited evidence to guide how to choose among the various types of dressing for grade 2/3 RD
Blades et al., 2020	Economic evaluation	Investigate a cost-effectiveness analysis of a RCT in patients with head and neck cancer	N/A	See Chan et al., 2019	Conducted robust economic evaluation for both prevention (using StrataXRT versus standard care), and for costs related to RD treatment First cost effectiveness analysis for StrataXRT that incorporated nursing and other resources used for standard RD prevention methods Discussed implications for clinical decision makers	Willingness-to-pay thresholds for preventing RD unknown Does not assess the financial burden on patients	No cost benefits for using StrataXRT identified when factoring in nursing, medical and allied health labor costs and resources Limiting patients to one 50-g tube of StrataXRT is more cost effective across willingness-to-pay thresholds Average of $368.88 per StrataXRT patient and $390.72 per control patient, accounting for total labor costs Median of two 50-g tubes per StrataXRT patient
eviQ, 2023	Evidence-based Summary	To summarize the existing preventative and management interventions used for RD	N/A	N/A		Does not individually evaluate StrataXRT, as only silicone-based gels/films as a broad category are discussed Does not grade evidence or conduct bias assessment	Some evidence exists supporting the use of silicone-based film/gels to prevent or reduce the severity of RD in the irradiated area No strong evidence exists for how to treat RD, treatment should be tailored for each patient

ROB = risk of bias; RD = radiation dermatitis; HCP = health care provider; ROBINS-I = Risk Of Bias In Non-randomized Studies—of Interventions; RCT = randomized controlled trial; NR = not reported; N/A = not applicable; AMSTAR-2 = A Measurement Tool to Assess Systematic Reviews-2; RT = radiotherapy

review, and Table 2 outlines their results. Table 3 outlines the characteristics and results of the secondary articles identified in the critical review.

Systematic review of primary literature

Breast RT Site

In 2019, Chao et al. conducted an RCT comparing the efficacy of StrataXRT to Mepitel film for the prevention of RD in breast cancer patients receiving post-mastectomy chest wall RT [18]. Forty patients had a minimum of five weekly assessments and were included in the per-protocol analysis [18]. Lateral and medial halves of the irradiated skin were randomized to either Mepitel film or StrataXRT. The CTCAE was used to assess RD. No patient quality of life (QoL) or other patient-reported outcomes were assessed [18]. The maximum grade of acute RD was 30% grade 1 and 70% for grade 2 for the StrataXRT halves, and comparatively, the maximum grade of acute RD was 5% grade 0, 42.5% grade 1, and 52.5% grade 2 for the Mepitel film halves. None of the StrataXRT patients experienced grade 3 RD, while 2.5% of Mepitel film patients experienced grade 3 RD [18]. Incidences of moist desquamation were 12.5% (n=5/40) for StrataXRT, compared to 20% (n=8/40) for Mepitel film (p=0.099) [18].

An RCT by Ahn et al. (2020) (n=56) investigated the use of StrataXRT for the prevention of RD in post-lumpectomy breast cancer patients. However, seven patients left the study after being initially randomized to the StrataXRT group [16]. The strengths of Ahn et al.'s study included RCT study design and generally well-balanced clinical characteristics for each group [16]. Patients were randomized to either StrataXRT or X-derm moisturizer and were instructed to apply their respective agent to the treatment site at least twice a day starting on the first day of RT to four weeks post-RT. RD was assessed using physiological skin parameters such as the erythema index, melanin index, and trans-epidermal water loss as measured by a reflectance spectrophotometer, and using clinician and patient assessments such as CTCAE, RTOG, and Catterall skin scoring profile (CSSP) which is a 10-point scoring profile. However, researchers did not assess the effect of StrataXRT on patients' QoL [16]. No incidence of moist desquamation in either the StrataXRT or the control group was detected, likely related to a small sample size. There were also no statistically significant differences in clinician reported outcomes (CSSP, RTOG, and CTCAE) and patient-reported symptoms (including burning sensation, pain, itchiness, or dryness) between the two groups. However, a significant difference between groups was identified in the erythema index (p=0.008) and melanin index (p=0.015), both were greater in the X-derm group [16]. These differences subsequently disappeared, suggesting the noted skin effects were temporary without permanent sequalae.

An RCT by Omidvari et al. (2022) (n=100) investigated the use of StrataXRT for the prevention of RD in post-partial mastectomy breast cancer patients. The RTOG criteria were used to assess skin toxicity. This study randomized patients to StrataXRT or supportive care, which involved no preventive measure for RD [17]. The StrataXRT group was advised to wash the RT site two times a day with soap and water then apply the StrataXRT gel with a thickness of 1-2 mm. The skin was assessed using both quantitative (RD size measured via transparent paper per square centimeter) and qualitative (RTOG) assessment methods. This study also did not assess patient-reported outcomes, experiences, or QoL [17]. The incidence of grade 3 and 4 RD at the fifth week of RT completion was found to be significantly lower in the StrataXRT group (grade 3; n=2/50, 4%, grade 4; n=0/50, 0%) compared to the supportive care group (grade 3; n=23/50, 46%, grade 4; n=1/50, 2%). Overall, in all the weeks, except the fourth week, the differences of RD grades 2+ were statistically significant between the two groups ($p < 0.05$) [17].

Head and neck RT site

An RCT by Chan et al. (2019) ($n = 197$) assessed the efficacy of StrataXRT on the prevention of RD in head and neck cancer patients. This study randomized patients to StrataXRT or the standard care of 10% Glycerine (Sorbolene) [11]. There were no statistically significant differences between Brief Pain Inventory (BPI), itching, or Skindex-16 scores between groups [11]. The StrataXRT group demonstrated a 12% reduced risk of grade 2 skin toxicity (RRR = 0.876, 95% CI: 0.778–0.987, $p = 0.031$); and a 36% reduced risk of grade 3 skin toxicity (RRR = 0.648, 95% CI: 0.442–0.947, $p = 0.025$), after the adjustment for Cetuximab [11]. Cox regression analysis showed that patients receiving StrataXRT had 41.0% and 49.4% reduced risks of developing grade 2 and 3 skin toxicity respectively throughout treatment compared to the Sorbolene arm [11]. StrataXRT patients also experienced a delayed onset of RD symptoms, where 75% of patients took six weeks to develop RD, compared to five weeks in the control group [11]. A limitation of this study is in its single-blinded design; however, the outcome assessor was blinded so this limitation should have minimal if any impact on the primary endpoint. [11].

A feasibility study by O'Dell et al. (2018) ($n = 20$) assessed the ability of StrataXRT to prevent RD in ten head and neck cancer patients, compared to retrospective data on ten patients of similar cancer treatment and demographic characteristics using standard treatment for RD throughout RT [14]. Researchers also conducted a crude cost-analysis, and concluded that overall, less dressing and nursing resources were required with the use of StrataXRT for the

prevention of RD when compared to the standard treatment. Nearly all StrataXRT patients reported that the product was easy to use, was soothing on the skin, and that they were mostly or completely satisfied with the experience [14]. A major limitation of this study is that only one-week post-RT follow-up data was available, as the worst skin outcomes such as dry and moist desquamation tend to occur two to four weeks post-RT [22]. Also, retrospective data were used for the control group therefore the Radiation-Induced Skin Reaction Assessment Scale (RISRAS) was only completed by the patients receiving StrataXRT. Strengths of this study include that there were similar population characteristics between the StrataXRT and control groups, and all the scoring was undertaken by a single assessor allowing for a consistent assessment. There was a minimal difference in the incidence of moist desquamation between the StrataXRT group ($n=6/10$, 60%) and control group ($n=8/10$, 80%), but with longer time until onset and faster recovery than control group [14].

Rutten (2021) ($n=55$) conducted a feasibility study on the use of StrataXRT for the prophylaxis of RD in head and neck cancer patients compared against Fatty E Cream [15]. Patients found StrataXRT easy to use and comfortable but did report some discomfort due to stickiness of the gel [15]. Additionally, patients reported discomfort when applying StrataXRT on tender or painful skin [15]. This study assessed both the HCP and patient data on the use of StrataXRT. A limitation of Rutten's study is the low rate of CTCAE scores (only 41% of participants) recorded. Therefore, results collected from Rutten's study must be interpreted with caution. Other limitations include that there was no randomization and retrospective data was used to create the control group. The authors reported a noticeable difference in the rate of moist desquamation between the StrataXRT group ($n=25$) and the retrospective control group ($n=30$), as measured using the RISRAS [15]. However, they noted that the significance of this finding was difficult to determine [15]. Using the CTCAE, no significant difference was found in the incidence of grades 0–2 RD between the two groups [15]. However, rates of grade 3 RD were 11% higher in the control group ($n=6/30$, 20%) than the StrataXRT group ($n=2/25$, 9%) [15].

Multiple/unspecified RT sites

Bryant et al. (2019) (n=56) conducted a feasibility study assessing the use of StrataXRT for the prevention and management of RD. A total of 56 patients with head and neck, breast, pelvis, skin, and lung cancer were treated with curative intent in the head and neck region [21]. StrataXRT was applied at least twice daily from the first day of RT and continued until RD resolved. Limitations of this study include that there was no randomization or stratification, no patient-reported outcomes, and the assessment tool used by HCPs was not specified. Bryant et al. found that acute grade 2+ was detected in 58.9% of patients, while acute grade 3+ RD was detected in 10.7% of patients [21].

A case series by Villandiego et al. (2018) ($n=5$) examined the use of StrataXRT for the treatment of RD in five patients with tongue, rectal, or submaxillary gland cancers. This was the first study to investigate the use of StrataXRT for treating RD, as use of StrataXRT began when a patient developed grade 2 + erythema, pruritus, and/or desquamation. However, this study had a limited sample size with no control group. Additionally, it assessed patients receiving combined cancer therapy, and could not differentiate whether the toxicities were more related to chemotherapy or RT [19]. The researchers did not provide information on the questionnaires or report the method of skin assessment, nor did they assess patient reported outcomes or the product's effect on QoL. Villandiego et al. argued that for this limited case series StrataXRT reduced the skin's inflammatory response [19].

An exploratory study by Quilis et al. (2018) ($n=54$) assessed the treatment of RD in patients undergoing RT for different cancer types. In their per protocol analysis, only 28 patients were included. Another limitation is the lack of a prospective control group and the unblinded HCP-conducted skin assessments [20]. However, a strength of this study is the used of patient experience measurement tools such as RISRAS, to evaluate the patient's QoL. The patient RISRAS component demonstrated a decrease in pain by 20.5% ($p=0.005$), itchiness by 22.2% ($p=0.002$), and burning sensation by 24.7% ($p=0.003$) [20]. The researcher component of the RISRAS demonstrated a decrease in erythema in the irradiated zone by 20.6% ($p=0.015$) after using StrataXRT and the overall RISRAS score decreased by 16.9% by the end of RT (p=0.004) [20]. Based on a five-item Likert scale, HCPs also reported a significant increase in skin hydration (26.0%; $p=0.021$), and a significant decrease in inflammation compared to the start of RT (−28.9%; $p=0.011$) [20]. A product evaluation sheet was completed by patients after treatment completion. Fifty percent ($n=8$) of respondents considered the products' ease of use "excellent," and 44% ($n=7$) considered the products' comfort "very good". Overall, 82% of patients reported their perception of the overall experience to be either "very good" or "excellent" [20].

Review of secondary literature

Many of the secondary articles grouped StrataXRT with other interventions such as semi-permeable dressings [23, 24], wound dressings [25, 26], silicone-based products [6, 27–29], barrier films [5, 30–32], or even incorrectly assigned it as a hydrogel [10]. These publications generally made either a weak recommendation for these groups

of interventions or encouraged further research to be done, noting the lack of sufficient strong evidence. Some reviews and guidelines however, individually evaluated and assessed StrataXRT as a tool to prevent/manage RD.

A network meta-analysis by Kao et al. (2022) assessed RCTs that investigated the topical prevention of RD in head and neck cancer patients. The review included 14 studies with a total of 1304 participants. A Risk of Bias tool (ROB) was used to evaluate the quality of RCT and was evaluated separately by two authors to reduce bias [33]. The meta-analysis indicated that olive oil (odds ratio (OR) = 0.18, 95% CI = 0.03–0.95) was the only effective regime compared to usual care, and effects of all other topic agents including StrataXRT (OR = 0.48, 95% CI = 0.15–1.54) were not found to be statistically significant [33]. Overall, the study found there is inadequate evidence to make recommendations for preventing RD [33].

Kiprian et al. (2022) conducted a review investigating various forms of RD prevention and treatment [34]. While this study discusses a variety of novel methods of RD prevention and treatment, it does not make any comparisons between these methods and their strengths/weaknesses, provide any recommendations, nor does it conduct ROB or quality assessments for the included studies. Overall, the authors concluded that StrataXRT is promising for RD prevention [34].

Solanki et al. (2021) provided guidelines relating to the treatment of genitourinary malignancies and RT [35]. As a part of these guidelines, the use of StrataXRT was discussed. This study incorporated expert opinions and the provision of recommendations for the use of StrataXRT. However, the discussion on StrataXRT and treatment of RD was limited, and there were no comparisons made to other forms of RD treatment/prevention. The authors reported that they have seen significant reduction in erythema in patients using StrataXRT and recommend patients with RD in the genitourinary regions to apply the product twice daily [35].

Bailey et al. (2021) created the practice consensus statement for the MD Anderson Cancer Center on skin management for head and neck radiation [36]. Majority opinion of the Texas MD Anderson Cancer Center experts in head and neck radiation oncology guided this practice consensus. They recommended cream emollients and/or silicone gels, topical steroids such as triamcinolone 0.1% cream and mometasone furoate 0.1% cream for the prophylaxis of RD [36]. Notably, StrataXRT is preferred among the existing silicone gels due to available published data [36].

Blades et al. (2020) conducted the first cost-effectiveness analysis for StrataXRT that incorporated nursing and other resources used for standard RD prevention, based on the results of Chan et al.'s RCT. The authors conducted robust economic evaluation for prevention and costs related to RD treatment and discussed implications for clinical decision makers. However, the willingness-to-pay thresholds for preventing RD were not identified in this study, as well as the financial burden on patients as products were provided to patients within a trial setting [37]. Blades et al. found that StrataXRT patients required fewer nursing occasions of service managing RD than the Sorbolene patients [37]. Wound management consumable costs also favoured StrataXRT (b = 41.0 95% CI: 17.1–64.9, $p = 0.001$). The incremental cost-effectiveness ratio for StrataXRT versus Sorbolene was estimated at $760.24 AUD additional cost per grade 3 RD prevented. However, the study found no cost benefits for using StrataXRT once all labour and care resources were factored in [37].

Discussion

The results of the systematic review demonstrated that the current body of evidence is not sufficient to make strong recommendations on the use of StrataXRT for the prevention and treatment of RD. However, existing literature warrants further research on StrataXRT. There is significant heterogeneity in study designs and sample sizes among the current clinical trials assessing the efficacy of StrataXRT in preventing and treating RD. Often, there is no direct comparison between the different dressings and topical agents that prevent and treat RD. This critical review also found that the secondary studies could not draw solid evidence-based conclusions regarding the use of StrataXRT. Generally, clinicians are recommended to consider implementing silicone-based products including StrataXRT at their discretion.

In summary, Chan et al., Chao et al., and Omidvari et al. produced positive results, as they all detected a decrease in the CTCAE grade 2/3 RD and moist desquamation rates of the StrataXRT arm compared to their respective standard of care [13, 17, 18]. Conversely, Ahn et al., O'Dell et al., and Rutten et al. reported no significant differences in the CTCAE or RTOG grades between control group and group given StrataXRT [14–16]. Cross-study comparison is difficult as Ahn et al. and Omidvari et al. also quantified the severity of RD using melanin index and erythema index, and size of RD area respectively, which is not measured in the other studies [16, 17]. Another issue was the use of a per-protocol analysis in some of the studies including Chao et al., Ahn et al., and Rutten et al. [15, 16, 18]. Attrition bias may arise if patients who are more adherent with the assigned treatment differ in characteristics. These articles also studied different cancer types with varying irradiated sites. Furthermore, the studies on breast cancer and head and neck cancer used StrataXRT for prophylaxis, while the studies on multiple cancer sites used it for treatment of severe RD. All these differences in study design make it challenging to meaningfully compare their results.

RD has a major impact on QoL of cancer patients who require RT, and may interfere with anti-cancer therapies, thus potentially reducing their effect [2]. To address this issue and the current controversies and help patients suffering from RD, this review summarized the available evidence for StrataXRT. The findings of this review recommend further adequately powered RCTs with robust methodology including patient and clinician assessments to determine the efficacy of StrataXRT in preventing/treating RD. This is essential to improve the QoL of patients and identify which groups of patients would benefit most from StrataXRT. Further skin-specific QoL measures that will be sensitive to detect changes in people experiencing RD need to be developed and validated [11]. All these will potentially guide the development of interventions for the prevention/management of RD. This is essential to improve the QoL of patients and identify which groups of patients would benefit most from StrataXRT.

Furthermore, the guidelines and reviews examined in this critical review demonstrate that a gold standard for RD in various cancer sites receiving RT is currently lacking. Generally, there is a weak recommendation for the use of StrataXRT, due to the lack of strong evidence and well-designed trials, however many reviews/guidelines note the practical utility of StrataXRT. For example, The International Society of Nurses in Cancer Care commented in their guidelines for RD that film forming gels for the head and neck region are potentially useful due to the mobility of the neck and the ability to be applied to facial hair [27]. StrataXRT is also shown to be noninferior to the standard of care in terms of economic value, and a decrease in the need for HCPs' time and resources [37]. This critical review recommends further research on StrataXRT, and the incorporation of critical discussion on StrataXRT in further reviews and guidelines.

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s00520-023-08190-8.

Author contributions M.G. performed extraction of studies, wrote the main manuscript text, and prepared all figures. S.A. performed screening, extraction, prepared all tables, and helped write the manuscript. S.S. participated in title and abstract screening, full-text screening, and resolved conflicts in screening. S.K. and T.R. helped prepare table 1 and 2 and checked data extraction. P.H., M.O., J.Y., and T.B. checked data extracted from the studies, the analysis in the manuscript, and made corrections where needed. S.L., R.C., and E.C. conceptualized this work, supervised as joint senior authors, and edited the manuscript. All authors helped to edit the manuscript and commented on previous versions of the manuscript. All authors have read and approve the final version.

Funding Author Raymond J. Chan is one of the trialists for one included trial. He received funding support from Stratpharma TM for conducting the trial and education sessions. All other authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

Data availability The search strategy and results can all be found in the tables and figures in the manuscript. All included articles can be found referenced in the bioliography.

Declarations

Competing interests E.C. received the free supply of StrataXRT in a pilot study of StrataXRT in the prevention of radiation dermatitis in breast cancer. R.C. is one of the trialists for one included trial, he received funding support from Stratpharma TM for conducting the trial and education sessions. All other authors have no relevant competing interests to disclose.

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