Otago Spotlight Series
Cancer Research

Reducing Skin Damage caused by Radiation Therapy

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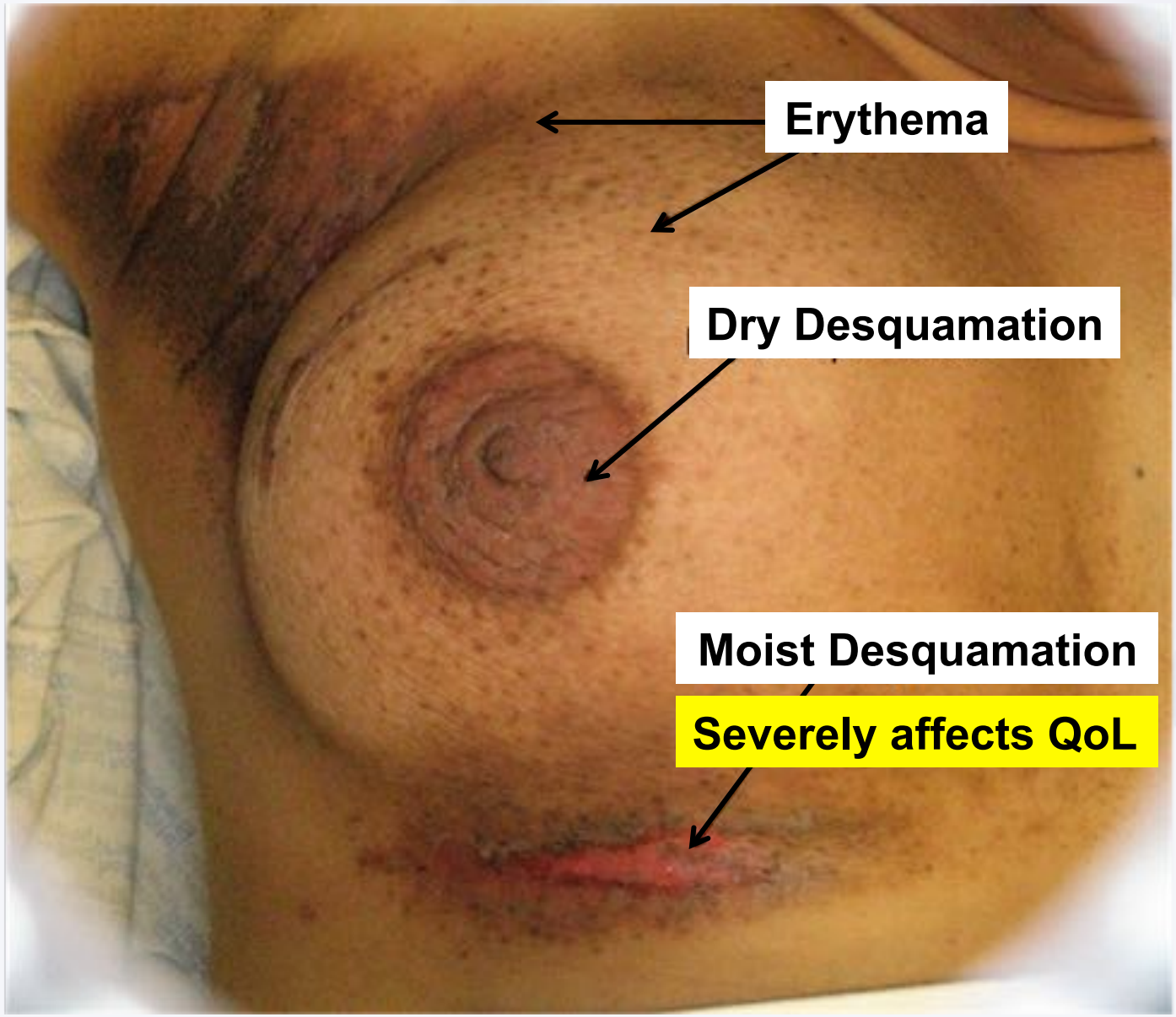
Rationale

Radiation therapy causes skin reactions in many breast and head & neck cancer patients

- RT kills both cancer and healthy cells by damaging their DNA
- RT aims to deliver a lethal dose to the tumour whilst sparing healthy tissues
- A high skin dose is unavoidable when treating tumours close to the skin

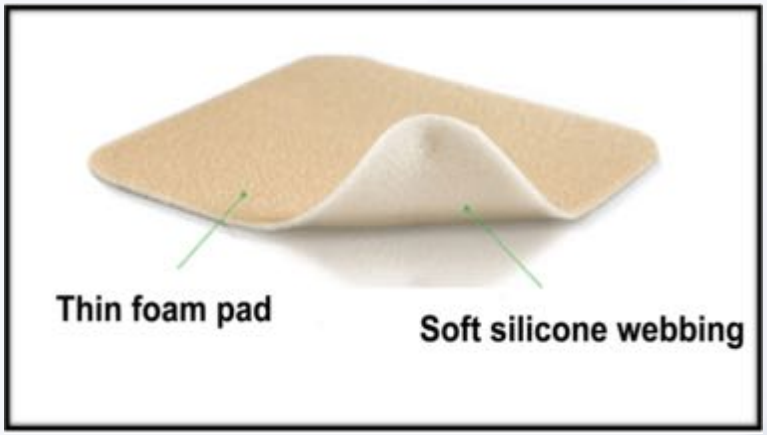

Erythema
Dry Desquamation
Moist Desquamation
Severely affects QoL

No standard treatment; mostly based on anecdotal or historical evidence

Soft silicone dressings

- Inert protective barrier
- Adhere to healthy skin but not open wounds
- Well tolerated during RT

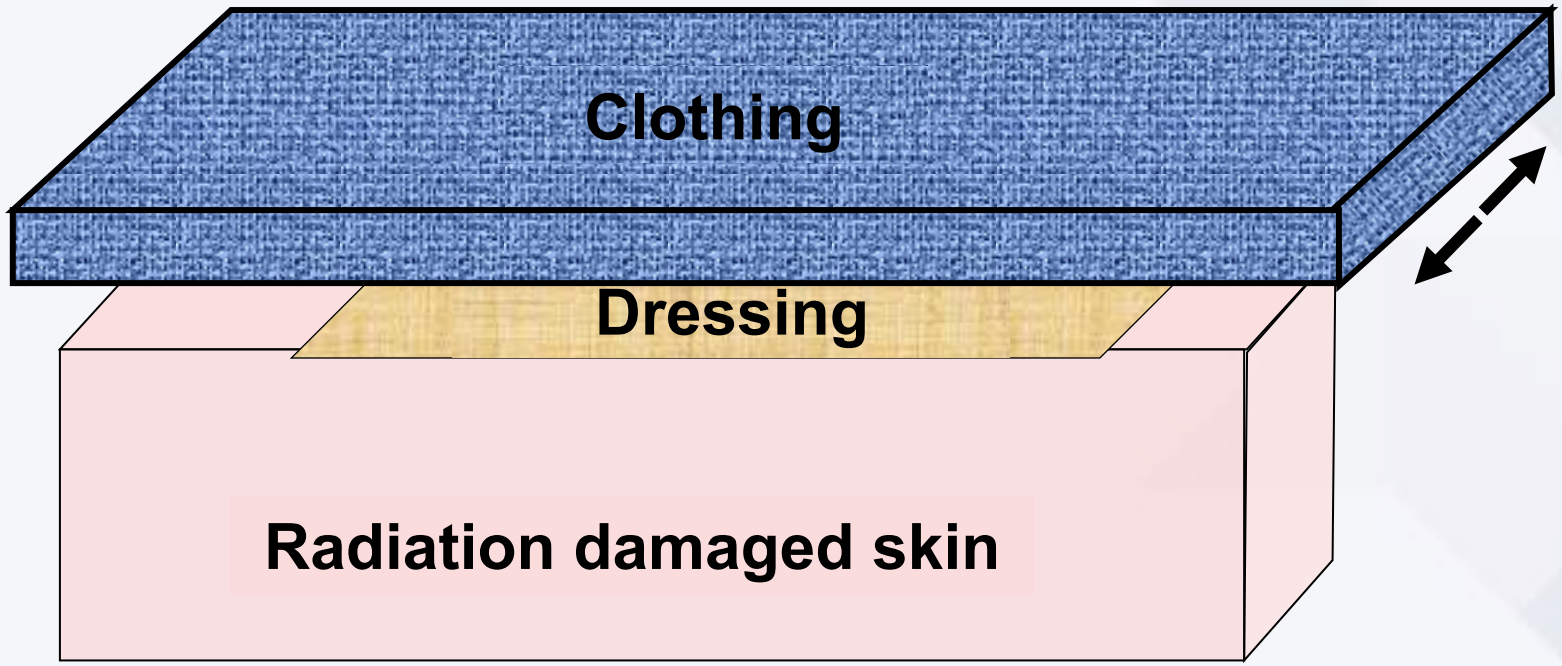
McBride et al. Cancer Nurs (2008)



Hypothesis

Close adherence to creases in the skin prevents friction of radiation-damaged skin by clothes/other body parts

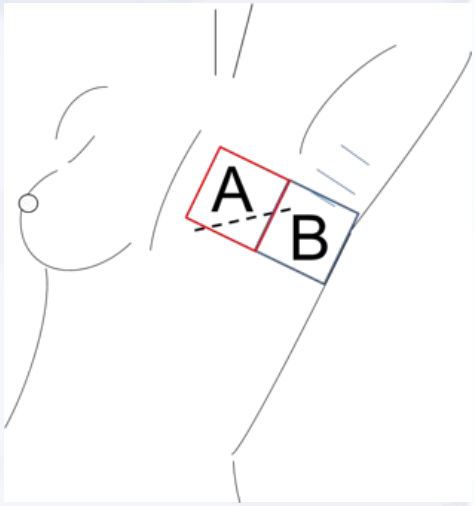
Mechanism of Action



Management trials

In-patient controls

- Divide skin area with erythema into 2 equal halves
- Randomize one half to dressings, the other to control cream
- Avoids potential confounding by patient- and treatment-related factors



RISRAS: Radiation Induced Skin Reaction Assessment Scale

(Noble-Adams. Br J Nurs. 1999;8(19):1305–12)

More sensitive than standard scoring systems such as RTOG

- Has patient component
- 3x a week during tmt, 1x a week for 4 weeks after tmt

RTOG Acute Radiation Morbidity: Skin *				
Grade 1	**Grade 2A**	**Grade 2B**	**Grade 3**	**Grade 4**
Follicular, faint or dull erythema; dry desquamation	**Tender or bright erythema**	**patchy moist desquamation**	**Confluent moist desquamation other than skin folds**	**Ulceration; haemorrhage; necrosis**

*Cox et al. Int J Radiat Oncol Biol Phys. 1995;31(5):1341–6.

- Basically 3 grades (necrosis very rare)
- Different severities together in the same grade
- Very difficult to pick up small differences

RISRAS (total scores between 0 and 36)*

Researcher Component (total scores between 0 and 24)

Erythema (E)	**0** Normal skin	**1** Dusky pink	**2** Dull red	**3** Brilliant red	**4** Deep red-purple
Dry Desquamation (DD)	**0** Normal skin	**1** (<25%)**	**2** (25%-50%)	**3** (50%-75%)	**4** (>75%)
Moist Desquamation (MD)	**0** Normal skin	**1.5** (<25%)	**3.0** (25%-50%)	**4.5** (50%-75%)	6 (>75%)
Necrosis (N)	**0** Normal skin	**2.5** (<25%)	**5.0** (25%-50%)	**7.5** (50%-75%)	**10** (>75%)

Patient Component (total scores between 0 and 12)

Symptoms	**Not at all**	**A little**	**Quite a bit**	**Very much**
*Do you have any **tenderness, discomfort** of **pain** of your skin in the treatment area?*	**0**	**1**	**2**	**3**
*Does your skin in the treatment area **itch**?*	**0**	**1**	**2**	**3**
*Do you have a **burning sensation** of your skin in the treatment area?*	**0**	**1**	**2**	**3**
*To what extent has your skin reactions and your symptoms affected your **day to day activities**?*	**0**	**1**	**2**	**3**

Pilot study: thin silicone foam dressing

Single centre; 30 women who had not had a mastectomy

30% decrease in severity of erythema

(p<0.001: ANOVA and Wilcoxon signed rank test)

Diggelmann et al. The British Journal of Radiology, 83 (2010), 971–978)

Stage III RCT: thin silicone foam dressing

Multicentre; 80 post-mastectomy patients

40% Decrease in skin reaction severity

(p<0.001: ANOVA, Wilcoxon signed rank test)

Paterson et al., Journal of Cancer Science and Therapy 4(11) 347-356 (2012)

Thin Foam dressings are not ideal

- Do not decrease the % of people developing moist desquamation when used when erythema is present
- Fall off in shower or when perspiring
- Must be removed during RT
    - not transparent: can't see tattoos
    - have a small bolus effect (0.5mm)

Superior Option: Transparent Film?

- Same silicone contact layer but with breathable film
- Thinner, transparent and more sticky
- Negligible bolus effect (<0.1mm)

Stage III RCT: Transparent Film Prevention Trial Dunedin

Participants

- n=80
- **Mastectomy or lumpectomy**
- No systemic disease
- No previous RT
- Able to attend follow-up
- Good performance status

Assessment

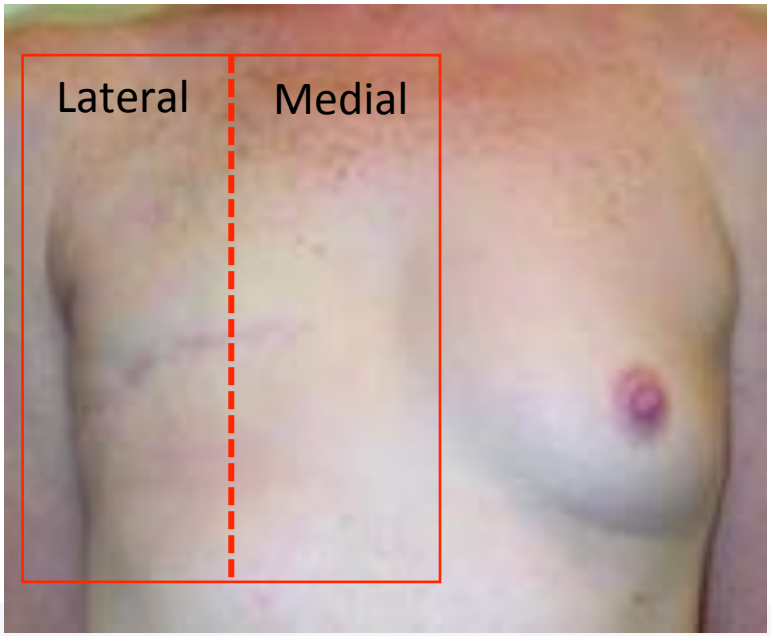
RISRAS

- 3x week during RT
- 1x week post-RT for 4 weeks

Day 1 Radiation Treatment

↓

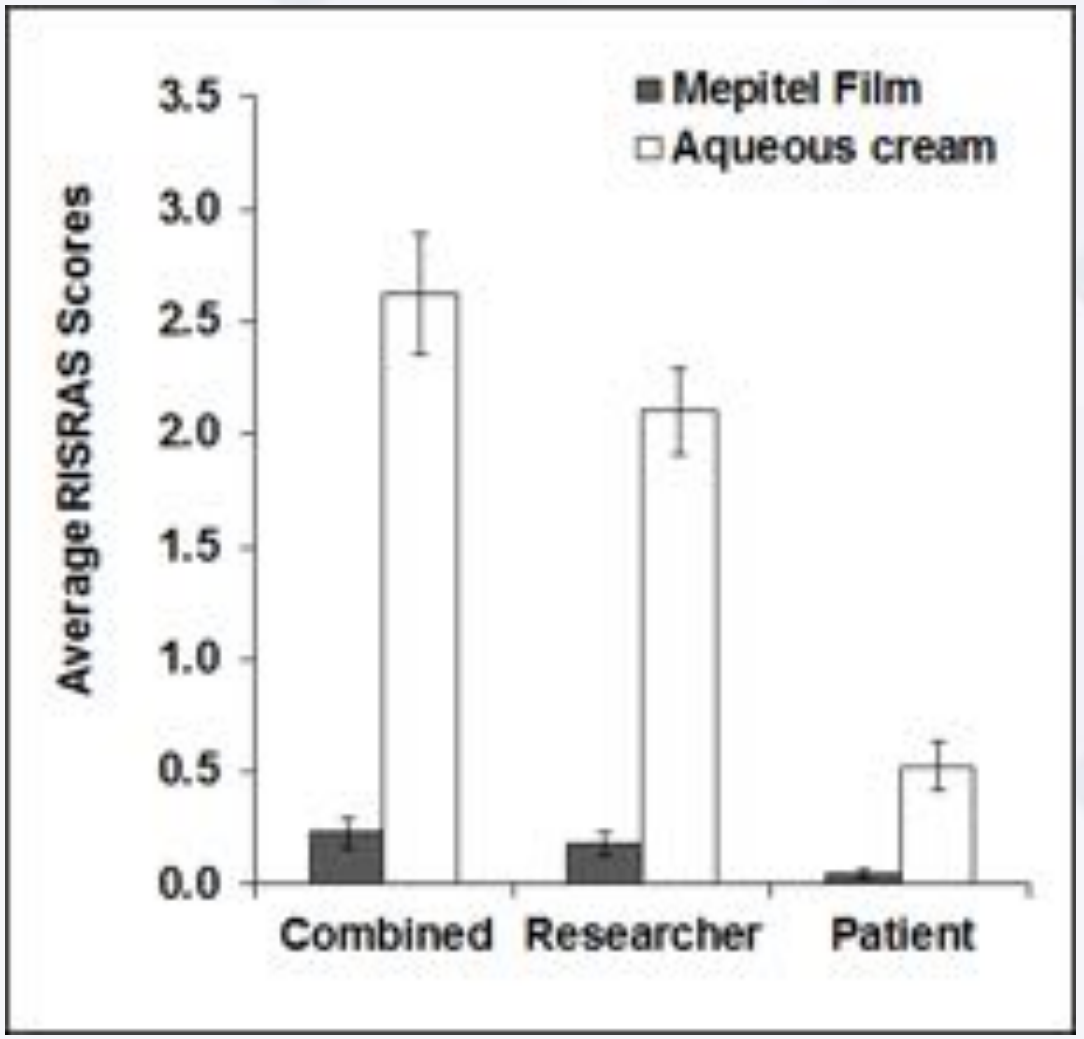
In-Patient Randomisation



Results
n=78

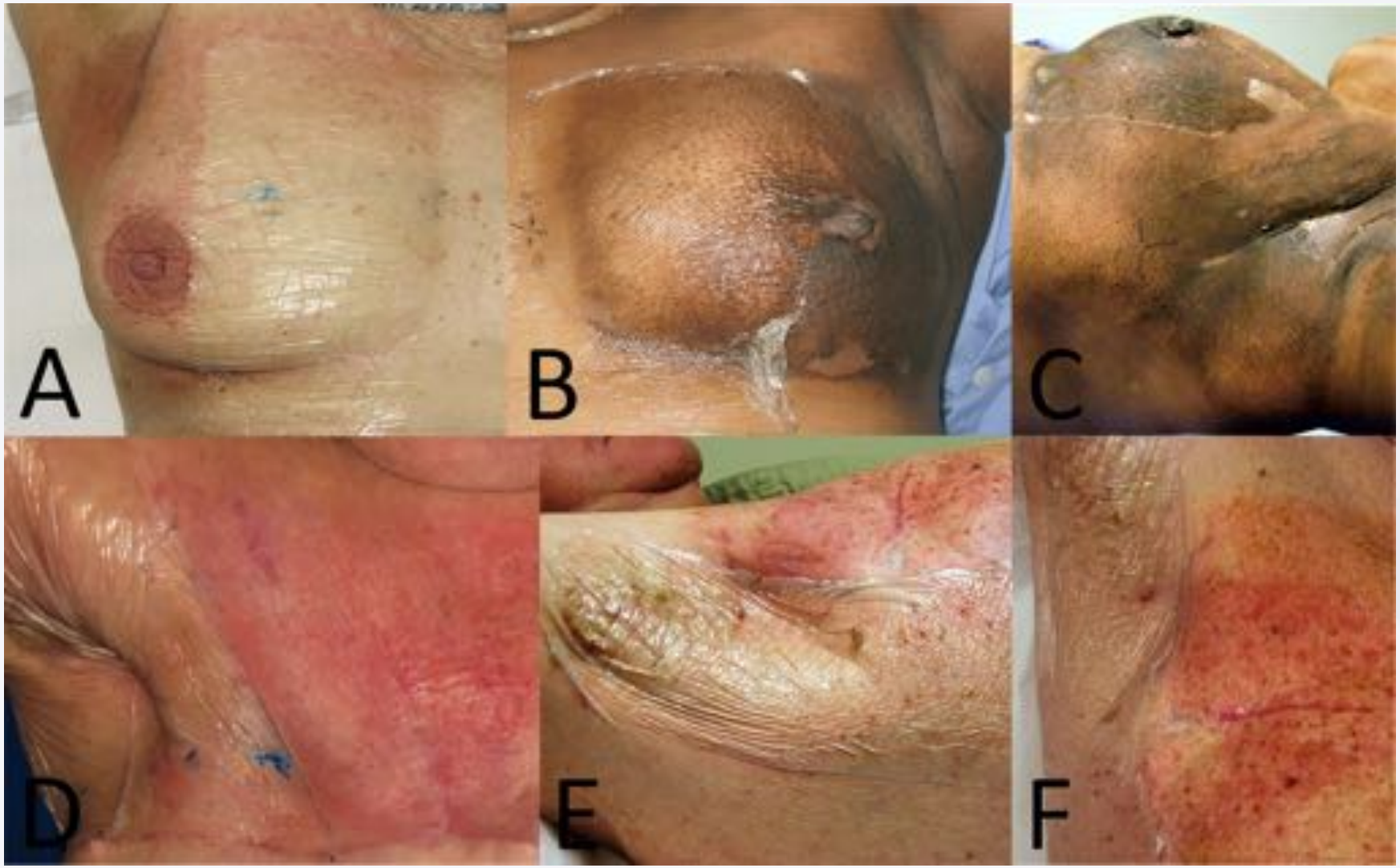
Decrease in severity> 90%

(p<0.001: ANOVA,
Wilcoxon signed rank test)



Herst et al, Radiotherapy and Oncology 110 (1): 137-143 (2014)

No Moist Desquamation under the Film



In Conclusion….

1. **Soft silicone dressings prevent friction and thus minimize skin reaction severity during RT**

2. **Most effective when used prophylactically: from the start of RT**

The Film is sponsored in NZ by PHARMAC (as a level I device)
Most (but not all) NZ DHBs and several hospitals in Australia, Canada, Europe and China are now using the Film as part of standard skin care for breast cancer patients.

What is next?

Test the Film in H&N patients

- Prophylactic trial: apply Film from day 1 of RT
- Multinational RCT:

  2 centres in NZ (Christchurch, Dunedin: recruiting)

  1 centre in Canada (Calgary, Alberta: submitted to ethics)

  2 centres in China (Nanjing, Hangzhou: preparing for ethics)

Acknowledgements

Trial Participants

Staff from Departments:

Southern DHB

Capital and Coast DHB

Mid-Central DHB

Auckland Regional Oncology

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otago.ac.nz/cancer-research