



Australian Government

**Rural Industries Research and
Development Corporation**

Tea Tree / Hydrogel Dressings Used in Wound Care

**A repeated measures comparative study
of a tea-tree oil and a pawpaw cream
dressing**

**A report for the Rural Industries
Research and Development Corporation**

**By Gary Bain, Mrs Hilary Kuwahata,
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Foreword

Radiotherapy skin reactions cause the patient discomfort and irritation. Little empirical evidence exists which defines best practice in relation to topical agents or dressings.

This project tested the efficacy of a tea-tree / hydrogel wound dressing (known to provide rapid cooling and fast relief of all skin reactions) to induce pain relief and healing of skin reactions and wounds. This dressing has been compared to a control group receiving another commonly used dressing.

The results from this study will ultimately impact on the comfort and well-being of patients following radiation treatment.

Although the sample size was small, the trend suggests that the TTO dressing is a product which has positive impacts on the skin integrity and comfort of radiotherapy patients, and therefore improves their quality of life.

It is recommended that a comparative multicentre product trial is carried out to determine product effectiveness across clinical settings, thus evaluating the product's suitability to provide a standardised approach to skin reaction management.

This project was funded from industry revenue which is matched by funds provided by the Australian Government

This report is an addition to RIRDC's diverse range of over 1200 research publications. It forms part of our Emerging New Industries R&D sub-program which aims to support the development of an environmentally sustainable and profitable Australian tea tree oil industry that has established international leadership in marketing, in value-adding, and in product reliability and production.

Most of our publications are available for viewing, downloading or purchasing online through our website:

- downloads at www.rirdc.gov.au/fullreports/index.html
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Peter O'Brien

Managing Director

Rural Industries Research and Development Corporation

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The research was undertaken by Sydney Adventist Hospital in conjunction with Rye Pharmaceuticals who manufacture the dressings and Byron Bay Essential Oils who produce the tea tree oil used in the dressings. Both companies have contributed financial support to the project as well as contributing in kind to the research and development which has already been carried out in the production of the dressing. The Hospital has entered into a confidentiality agreement with these companies.

The radiation therapists and secretarial staff of the Sydney Radiotherapy & Oncology Centre have been very helpful in instigating procedures for the smooth running of this project.

Dr Gordon Adler, Professor John Boyages, Dr Edward Sun and Dr Jayasingham Jayamohan assisted with the collection of data.

A special thankyou to Lisa Snodgrass and Paulette Bakker, the registered nurses, who assisted in many ways with the preparation of the collection process, patient recruitment, questionnaire distribution, and performing skin assessments and dressings.

We also thank Dr Ross Grant from the Australasian Adventist Health Research Institute for his support and advice on the project as well as Dr Gillian Heller from the Australasian Adventist Health Research Institute for her analysis of the data.

Elaine Lumsdaine from the Sydney Adventist Hospital Library assisted with the location of literature for the study.

Abbreviations

TTO:	Tea Tree Oil
RISRAS:	Radiation-Induced Skin Reaction Assessment Scale
RTOG:	Radiation Therapy Oncology Group
RN:	Registered Nurse
VAS:	Visual Analogue Rating Scale
ID:	Identification

Contents

Foreword	iii
Acknowledgments	iv
Abbreviations	iv
Executive Summary	vi
1 Introduction	1
Literature Review	1
Radiation Skin Reactions	1
Tea tree oil.....	2
Pawpaw (Carica papaya) Applications.....	2
Clinical Intervention.....	3
2 Objectives	3
3 Methodology	3
3.1 Research Design.....	3
3.2 Setting	4
3.3 Sample.....	4
3.3.1 Treatment group (TTO).....	5
3.3.2 Control group (PP)	5
3.4 Procedure.....	5
3.5 Ethical Considerations	6
3.6 Data collection	6
3.6.1 RTOG Scoring System For Acute Radiation and Morbidity	6
3.6.2 Visual Analogue Pain Scale	6
3.6.3 The Radiation-Induced Skin Reaction Assessment Scale	6
3.6.4 Demographic Questionnaire (Appendix 4)	6
3.6.5 Photographs	6
3.7 Analysis.....	7
4 Results 7	
4.1 Analysis of Dressing Data.....	7
4.1.1 Radiation Induced Skin Reaction Assessment Scores.....	7
4.1.2 RTOG Scores	9
5 Discussion of Results	10
6 Implications	10
7 Recommendations	10
8 Appendices	11
8.1 Information Letter	11
8.2 Consent Form	12
8.3 Skin Care Form	13
8.4 Demographic Questionnaire	14
8.5 Weekly Assessment Questionnaire	19
8.6 Decision Making Protocol	23
9 Glossary	24
10 References	25

Executive Summary

- **What the report is about**

Radiotherapy is a fundamental treatment modality for cancer. It is estimated that at least 60% of patients being treated for cancer will receive radiation (Naylor & Mallett, 2001). As many as 95% of these individuals will experience a skin reaction (Porock & Kristjanson, 1999). The reaction's presentation will to some degree impact on the physiological, emotional and financial well-being of the patient, and can be significant enough to warrant cessation of the radiation treatment.

Inflammation and skin trauma is a consequence of cellular and DNA damage, largely brought about by the release of free radicals and reactive oxygen species during treatment (Bryant, 2000). Recent investigations into the biochemical properties of tea-tree oil (*Malaleuca alternifolia*) have noted its capacity to down regulate inflammatory mediators and superoxide production, thereby reducing cutaneous tissue damage (Finlay-Jones & Hart, 2001).

This finding encouraged the authors of this paper to examine the effect of a tea-tree oil hydrogel dressing (Rye Pharmaceuticals) on skin reactions to acute radiation.

Of primary interest was the tea tree oil's impact on the patient's clinical presentation and symptom management, as well as observing any variance in the skin reaction's rate of conversion to more severe tissue damage over the time of radiation treatment.

- **Who is the report targeted at?**

The aim of skin care is to help the patient manage their discomfort so that they are able to complete an optimal course of treatment. Unfortunately, little empirical evidence exists which defines best practice in relation to topical agents or dressings. Consequently, skin care varies enormously between institutions and practitioners.

The intention of this investigation was to determine whether the TTO hydrogel dressing, with its anti-inflammatory and anti-microbial properties, could improve the symptom management of radiation skin reactions and reduce the incidence of dry desquamation converting to the confluent moist variety.

“Future research must be conducted to provide better evidence for prevention and treatment of acute radiation dermatitis, and novel therapies must be investigated” (Wickline, 2004).

- **Background**

As radiation doses accumulate, increasing numbers of basal cells are destroyed. The manufacture of epidermal cells is increasingly retarded, the skin's immune response is down-graded and melanin production limited. Lasting tissue and endovascular damage eventuates if the inflammatory process is prolonged. Advancing work done by Pippin and colleagues (1994), Finlay-Jones and Hart (2001) documented that tea tree oil contains substances which may selectively regulate cell function during inflammation and following topical application, control inflammatory responses to foreign antigens in the skin. They postulated that TTO enables white blood cells to remain fully active in an acute inflammatory response, whilst suppressing the inflammatory response thereby preventing tissue damage in a prolonged inflammatory state.

As radiation skin reactions are instigated and perpetuated by oxidative stress at the basal cell layer, it is hypothesized that the regular topical application of TTO from early in the radiation treatment may reduce the intensity, extent and duration of skin reaction.

- **Aims/Objectives**

The objective of this program is to develop a wound dressing using tea tree oil in order to take advantage of its anti-inflammatory and anaesthetic properties as well as its antimicrobial properties. It is proposed that this dressing should be targeted initially at the post radiotherapy burns market with a view to investigating its value in the wider wound care market at a later date.

The R&D objective is to conduct a clinical trial to produce valid data to support future marketing of the product.

- **Methods used**

Individual subjects were randomised into two experimental groups: the treatment group received TTO hydrogel dressings while the control group received pawpaw ointment. Both groups completed an initial demographic questionnaire following the first week of treatment. The patients then completed a patient symptom scale on a set day each week and their medical officer completed an adapted Radiation Therapy Oncology Group (RTOG) scoring scale for Acute Radiation Reactions. The attending RN also administered a health professional assessment scale.

Entry conditions were imposed in order to reduce the impact of independent variables such as different health agencies utilizing different interview techniques, support and philosophies of personnel. Persons with already complex or broken wounds were not asked to participate, as the dressings were not suitable for areas of broken skin.

The researchers did not want to compromise the study by using a product that had been implicated in skin reactions, therefore it was decided that sorbolene based creams should not be used in the study.

The trial was explained to the patient by the registered nurse and an information letter was given to them to read. Patients were allowed time to ask questions and the procedure and commitment was explained. Following this, if the patient agreed to participate, a consent form was signed. The patient was assured that they could withdraw from the study at any time without fear of their decision affecting their treatment. The patient was instructed by the registered nurses as to the appropriate skin care routine to aid optimal skin condition and also to prevent trauma to the skin in the treatment area. Following the patient's first week of radiation treatment the patient was asked to complete a short demographic questionnaire and a skin assessment was performed. Skin assessment was then carried out on a weekly basis throughout the course of radiotherapy, and photographs were taken once a dressing was commenced. The decision to commence the dressing protocol was based upon the clinical expertise of the RNs in the unit.

- **Results/Key findings**

This is the first time that TTO has been tested in this clinical setting, and the results of the trial suggest that it makes a clinical difference in some patients. This difference was enough to provide comfort to many of those who used it.

The analysis of the nurses' assessment scores indicated a consistent trend showing tea tree oil achieving better results than those using the pawpaw ointment; however these differences did not reach statistical significance possibly due to low sample numbers. Importantly this trend was also generally confirmed by the independent and blinded doctor's scores that again showed tea tree oil achieving slightly better results than the pawpaw ointment, statistical significance being achieved at week 4 (see graph 4.3). It is interesting to note that at assessment points during weeks 5 and 6 this trend reversed. This possibly suggests that the TTO dressing

is less appropriate later in the treatment period.

Anecdotally, both products had their positive and negative points. Both products were found by some to be irritating to the skin. TTO was found by some to be offensive in its odour, while pawpaw was found to be thick and greasy, causing staining of clothes requiring a combine dressing. The TTO dressing was however difficult to secure, falling off at times, but at other times became adherent to the skin with small skin tears occurring.

Positive qualities of both products were their soothing effect on the skin, both products reduced erythema and discomfort and enabled patients to continue with their normal daily activities. TTO dressings had the advantage of a cooling effect on the skin which patients found beneficial.

- **Implications for relevant stakeholders**

Notwithstanding the limited size, this study resulted in a consistent trend showing that the TTO dressing as a product impacted positively on radiotherapy patients' skin integrity and comfort and

therefore quality of life. Further to this the documented effect of reduction of tissue damage suggests that perhaps earlier use of this dressing may further reduce the signs and symptoms that we have seen in the study. This was not tested in this study as it was being piloted as an alternative to pawpaw, which is only applied once symptoms appear.

- **Recommendations**

The positive outcomes indicated in this study, for radiotherapy skin reaction, should be confirmed using a larger group possibly involving multiple centres.
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This larger trial may provide further evidence of the effectiveness of the Tea Tree Oil dressing in the clinical setting. Further, the trial should be designed in such a way as to determine the appropriate dressing regime for the use of this product by Radiation Oncologists and Radiotherapy nurses in the management of their patients.

The results of such a study may also indicate that the use of Tea Tree Oil hydrogel dressings is appropriate in the treatment of other wound types. It would be interesting to compare the application of a TTO product with the application of a product such as aloe vera, which is frequently applied earlier in the course of radiotherapy treatment.

In future studies utilizing these dressings the protocols must include the need to thoroughly moisten the dressing prior to removal if the patient finds that there is a tendency for the dressing to adhere to the skin.

In response to the comments regarding the odour of the TTO dressing, the manufacturers may need to investigate ways of reducing this concern.

1 Introduction

Radiotherapy is a fundamental treatment modality for cancer. It is estimated that at least 60% of patients being treated for cancer will receive radiation (Naylor & Mallett, 2001). As many as 95% of these individuals will experience a skin reaction (Porock & Kristjanson, 1999). The reaction's presentation will to some degree impact on the physiological, emotional and financial well-being of the patient, and can be significant enough to warrant cessation of the radiation treatment.

Inflammation and skin trauma results from cellular and DNA damage, largely brought about by the release of free radicals and reactive oxygen species (Bryant, 2000). Recent investigations into the biochemical properties of tea-tree oil (*Melaleuca alternifolia*) have noted its capacity to down regulate inflammatory mediators and superoxide production, thereby reducing cutaneous tissue damage (Finlay-Jones & Hart, 2001).

This finding encouraged the authors of this paper to examine the effect of a tea-tree oil hydrogel dressing (Rye Pharmaceuticals) on acute radiation skin reaction. Of primary interest was the tea tree oil's impact on the patient's clinical presentation and symptom management, as well as observing any variance in the skin reaction's rate of conversion to more severe tissue damage over the time of radiation treatment.

Literature Review

Radiation Skin Reactions

The dermis of the skin contains blood vessels, lymphatics, glands, nerves and hair follicles, which make up the supportive structure required for the epidermis to renew. The basal layer of the epidermis diffuses nutrients and gases from the dermal capillaries, thereby sustaining epidermal function. Cells active within the epidermis include Langerhans cells and melanocytes – being respectively involved in immune function and melanin production (Wells & MacBride, 2003).

The chromosomal DNA of the basal layer is particularly sensitive to radiation. Low doses of radiation cause oxidative stress, releasing histamine from damaged cells, which in turn produces an inflammatory response in the dermal vessels and surrounding tissue matrix. This produces oedema, erythrocyte extravasation and capillary dilatation (Bryant, 2000; Main, Hatcher & Meeks, 2004).

As radiation doses accumulate, increasing numbers of basal cells are destroyed. This stimulates the ingress of growing numbers of neutrophils, cytokines and proteases into the irradiated tissue. Free radicals and reactive oxygen species are triggered which attack unsaturated fatty acids, nucleic acids and structural proteins (Goldberg & McGynn-Byer, 2000; Wickline, 2004).

The manufacture of epidermal cells is increasingly retarded, the skin's immune response is down-graded and melanin production limited. Lasting tissue and endovascular damage eventuates if the inflammatory process is prolonged and arteriole obstruction arises from endothelial swelling (Sitton, 1992; Wells & MacBride, 2003).

Skin reactions tend to become visible around the second to third week of radiation, reaching a peak at the end or within one week of completion of therapy. Factors which exacerbate skin reactions include radiation with concurrent chemotherapy, recent and continued smoking, friction over the site of radiation, obesity, and possibly the use of products containing perfumes, zinc or silver. The intensity of the skin reaction is also related to variables such as radiation fraction, total radiation dose, the anatomic area irradiated, radiation type and individual differences between patients. (Barkham, 1993; Bolderston, 2003; Heggie et al, 2002; Macmillan et al, 2004; Wickline, 2004).

The Radiation Therapy Oncology Group (RTOG) produced a range of grading criteria to quantify and describe skin reactions. Reactions can range from mild erythema through dry desquamation to confluent moist desquamation where blistering, peeling and sloughing of the skin occur. At any one time it is possible to see a combination of erythema, dry and moist desquamation within a single treatment field (Porock, 1999; Trotti et al, 2000).

Moist desquamation indicates that the dermis is exposed because basal cell layer repair is not complete prior to skin shedding. The skin is moist with serum and the risk of infection is increased. The patient experiences pain and “burning.” Continued irradiation or an opportunistic infection can lead to extensive dermal damage or even necrosis. Approximately, 10-15% of patients succumb to moist desquamation (Blackmar, 1997; Porock & Kristjanson, 1999; Sitton, 1992; Wells & MacBride, 2003).

Tea tree oil

Tea tree oil (*Melaleuca alternifolia*) is a clear, colourless to pale yellow liquid, with a spicy odour and is insoluble in water. Tea tree oil [TTO] is lipophilic and is adept at penetrating the skin and mucous membranes. The active ingredients responsible for killing bacteria and fungi include terpinene-4-ol, alpha-terpineol and alpha-pinene. These substances act to produce inhibition of cell respiration and disruption of cell membrane permeability with the resultant leakage of potassium (Altman, 1991).

TTO has anti-microbial effect against organisms such as *Staphylococcus aureus*, Methicillin-resistant *staphylococcus aureus*, *Streptococci*, *Escherichia coli* and *Candida albicans*. Debate exists as to TTO’s capacity to kill *Pseudomonas aeruginosa* (Altman, 1991).

Most commercially available TTO preparations are diluted down to a 2-5% concentration. Reports demonstrate the effective use of this strength solution for conditions such as vaginal fungal infection, acne, impetigo, tinea pedis, boils and minor burns (Altman, 1991; Carson & Riley, 1993; Greig, 1999).

Studies by Pippin et al. (1994) and Finlay-Jones and Hart (2001) documented that terpinene-4-ol and alpha-terpineol may selectively regulate cell function during inflammation and following topical application, control inflammatory responses to foreign antigens in the skin. They postulated that TTO enables neutrophils to remain fully active in an acute inflammatory response, whilst suppressing monocyte inflammatory mediators thereby preventing oxidative tissue damage in a prolonged inflammatory state.

As radiation skin reactions are instigated and perpetuated by oxidative stress at the basal cell layer, it is hypothesized that the regular topical application of TTO from early in the radiation treatment may reduce the intensity, extent and duration of skin reaction.

Pawpaw (*Carica papaya*) Applications

Pawpaw (*Carica papaya* or Papaya) contains many biologically active compounds. The milky sap of an unripe pawpaw contains two main enzymes known as Papain and Chymopapain. Studies in the US show that fermented papaya extract has both antioxidant and immuno-stimulant properties (Nutranews, 2002).

Traditionally the juice, shoots and latex from the pawpaw plant have been used in herbal medicines. Topically, leaves have been used as dressings for wounds and skin conditions such as psoriasis (Herbal Remedies, 2005). Preparations have also been made available which allegedly “helps revive immune system parameters” (Nutranews, 2002).

Topically, the extracts from the pulp and seeds of the pawpaw fruit have been shown to have bacteriostatic properties when tested against *Staphylococcus aureus*, *Bacillus cereus*, *Bacillus subtilis*, *Escherichia Coli*, *Pseudomonas aeruginosa* and *Shigella flexneri* and other bacteria in vitro (Animal Science at Cornwell University, 2001; Purdue University, 1996). The plant is also seen to be a strong amoebicide when the latex extract is applied externally to burns, scolds and necrotic tissue in chronic wounds (Purdue University, 1996; Ayahuasca SpiritQuest, 2002).

Mikhailchik, et al (2004) demonstrated that treatment with a phytopreparation from the pawpaw plant accelerated wound healing and reduced the severity of local inflammation in rats with burn wounds. This is thought to be due to the inhibition of bacterial catalase activity, therefore increasing the effectiveness of phagocytic action against these organisms. The antioxidant activity of the preparation also decreased the risk of oxidative damage to tissues.

Pawpaw is also used in general skin care. Butterer and Chronis (1998) suggested that pawpaw revitalizes the skin, while Seigel-Maier (1999) identifies the papain enzyme as the product that exfoliates and restores the pH acid mantle of the skin.

Unfortunately there is little definitive research indicating the effect of this product on human skin in general and its possible role in skin care and treatment of radiation induced skin reactions in particular.

Clinical Intervention

The aim of skin care is to help the patient manage their discomfort so that they are able to complete an optimal course of treatment. However, little empirical evidence exists which defines **best practice** in relation to topical agents or dressings. Consequently, skin care varies enormously between institutions and practitioners. Fortunately, irrespective of the diversity of topical treatments, the majority of skin reactions heal within four weeks of the completion of radiotherapy. (Bolderston, 2003; Bruner & McGinn-Byers, 1993; Bryant, 2000; Macmillan et al, 2004; Main, Hatcher & Meeks, 2004; Wickline, 2004).

The only documented attempt at standardisation of topical dressing therapy in Australia is derived from the Australian College of Radiographers' website (2001). They recommend hydrocolloid dressings for light to moderate exuding wounds, such as patchy moist desquamation, whilst alginate sheets are recommended for confluent moist desquamation. It is also advised that dressings be removed for radiotherapy treatment since the dressing's additional volume can produce a bolus effect, which increases the radiation dose to the skin.

Wickline, 2004, states that "Future research must be conducted to provide better evidence for prevention and treatment of acute radiation dermatitis, and novel therapies must be investigated".

Radiation skin reactions impact on the quality of life for the majority of patients who undergo irradiation. The intention of the investigation into the topical application of the TTO hydrogel dressing is to determine whether this agent, with its anti-inflammatory and anti-microbial properties, can improve the symptom management of radiation skin reaction and reduce the incidence of dry desquamation converting to the confluent moist variety.

2 Objectives

The objective of this program is to develop a wound dressing using tea tree oil (TTO) in order to take advantage of its anti-inflammatory, anaesthetic and antimicrobial properties. It is proposed that this dressing should be targeted initially at the post radiotherapy burns market with a view to investigating its value in the wider wound care market at a later date.

The R&D objective is to conduct a clinical trial to produce valid data to support future marketing of the product.

3 Methodology

3.1 Research Design

A randomised, double blind, controlled repeated measures experimental design was utilised in this study. It consisted of a treatment group (TTO hydrogel dressing) and a control group (pawpaw ointment). Randomisation for the allocation of patients to groups was achieved by the registered nurses (RN) allocating the patients the next ID number on the list when they consented to participation in the study. Patients allocated even numbers were placed in the control group and those with odd numbers entered the treatment group. Both groups completed the initial questionnaire following the first week of treatment. The patients then completed a patient symptom scale on a set day each week and their medical officer completed an adapted Radiation Therapy Oncology Group (RTOG) scoring scale for Acute Radiation Reactions and the RN administered a health professional assessment scale.

Blinding was accomplished by not disclosing to the medical officers, radiotherapists or patients what was being used for skin treatment. Patients would remove their dressings prior to treatment and would

see the RN following the medical officer's review. Patients were also asked not to discuss their treatment with other patients in the waiting room.

The entry conditions (see table 3.1) were imposed in order to reduce the impact of independent variables such as different health agencies utilizing different interview techniques, support and philosophies of personnel. Persons with already complex or broken wounds were not asked to participate, as the dressings were not suitable for areas of broken skin. An understanding and ability to speak English was needed to be able to gain information on patient skin reaction and attain dressing compliance. Patients with a current mental condition or depression were also not included as this may have interfered with their ability to follow dressing instructions and may have impacted on their ability to describe their physical condition accurately for the study. Persons under 18 years were not asked to participate in this study, as this age group was not normally treated at the facility.

The researchers did not want to compromise the study by using a product that had been implicated in skin reactions, therefore it was decided that sorbolene based creams should not be used in the study.

Table 3.1: Entry criteria for the study

1.	Patients are to be having radiation to the Chest/Breast, Skin, or Head & neck area
2.	The patient has no existing skin reaction, rashes, broken skin in the area being treated
3.	The patient is not suffering from severe dehydration or malnourishment
4.	The patient is mentally well and able to cogently answer the questions being asked
5.	Patient is aged over 18 years

3.2 Setting

The Sydney Radiation Oncology Centre, on the grounds of the Sydney Adventist Hospital services around six hundred patients a year. Many of these patients are from the Sydney metropolitan area, however there are a substantial number of patients being treated from the Central Coast region. Patients are also treated from country areas such as Orange and many of these choose to stay at Jacaranda Lodge while being treated. The centre is serviced by 5 radiation oncologists, 21 radiation therapists, two registered nurses, and six administrative staff,

3.3 Sample

One hundred and one patients that filled the requirements for the study were randomly allocated to either the treatment or control group. Fifty-two were allocated to the treatment group and 49 to the control group.

A demographic questionnaire was completed at the end of the first week of treatment along with the first skin assessment. Of those choosing to participate six were men and 93 were women. This is predominantly due to the inclusion criteria. The mean age for the group was 58.4 years with ages ranging from 32 to 85 years. Sixty-eight percent were married (n= 69). Eighty percent (n= 81) lived with a spouse/partner or family/ close friend, while 15% (n=16) lived alone but had someone they could call on if they needed to. Eighty-nine percent (n=90) owned their own home while others either rented or had other arrangements.

Most of the participants were educated past high school (n=34) and 18 participants had attended university level education. Fifty-seven percent (n=76) of participants did not go out of the home to work, however 74% viewed themselves as in either a good to very good financial situation. Nineteen participants had one to two children under the age of 16 years at home to care for.

Five of the participants were smokers and the number of cigarettes smoked per day ranged between one and 25 with an average of seven per day.

Thirty-six people had had previous chemotherapy treatments and only two were currently on chemotherapy. Eighty-four participants had not experienced a loss of appetite at the beginning of the study and only eight participants had diabetes. Ten participants indicated moderate to severe fatigue at the beginning of the study.

Thirty-four of those taking part in the study indicated they had product sensitive skin and these products ranged from cosmetics and soaps to sun creams and Elastoplast (Smith and Nephew Australia) type tapes. Twenty-nine patients classified their skin type as olive to fair while thirty-eight classified themselves as fair skinned. With the use of the visual analogue rating scale (VAS), where patients were asked to rate how quickly they would burn if they were exposed to the sun (0 = don't burn to 10 = burn very quickly) 35 participants indicated they burn very quickly (a score of 8-10) when exposed to the sun. Scores were measured across the whole continuum with a mean score of 5.68. Skin pain was also measured on the visual analogue rating scale (VAS) 0 = no pain to 10 = worst pain imaginable. Scores were measured across the whole continuum with a mean score of 0.37 for the pain experienced at this stage of their treatment.

Of the 101 patients consenting to the study three withdrew prior to commencement and another seven withdrew due to changing their minds as to the cream they preferred to use. These products included cortisone creams, which they had at home or purchased over the counter at the chemist, aloe vera products and sorbolene cream. Two other patients withdrew due to illness and inability to attend assessments.

3.3.1 Treatment group (TTO)

Fifty-two of the patients, allocated with odd identification numbers, were allocated to the treatment group known as **Dressing B** and received the **Tea Tree Oil Dressing**. If a skin reaction occurred in these patients they would receive the tea tree oil dressing. Instruction was given in its use. This included storage, application and removal of the dressing.

A total of 22 patients developed a skin reaction and so were given the TTO dressing.

3.3.2 Control group (PP)

Forty-nine patients, allocated with even identification numbers, were allocated to the control group or **Dressing A** and received **Pawpaw (PP) Ointment**. If a skin reaction occurred in these patients they would receive the pawpaw dressing. This was the dressing routinely used at the unit and the usual instruction was given in its use. This included storage and application of the ointment. This was called a dressing as it required the application of a combine pad to protect the patient's clothes from the ointment.

A total of 17 patients developed a skin reaction and so were given the Pawpaw dressing.

3.4 Procedure

The trial was explained to the patient by the registered nurse and an information letter (Appendix 1) was given to them to read. Patients were allowed time to ask questions and the procedure and commitment was explained. Following this, if the patient agreed to participate, a consent form (Appendix 2) was signed. The patient was assured that they could withdraw from the study at any time without fear of their decision affecting their treatment. The patient was instructed by the registered nurses as to the appropriate skin care routine to aid optimal skin condition and also to prevent trauma to the skin in the treatment area (see skin care form Appendix 3).

Following the patient's first week of radiation treatment the patient was asked to complete a short demographic questionnaire (Appendix 4), and a skin assessment (Appendix 5) was performed. Skin assessment was then carried out on a weekly basis throughout the course of radiotherapy, and photographs were taken once a dressing was commenced.

The decision to commence the dressing protocol was based upon the clinical expertise of the RNs in the unit (Appendix 6).

3.5 Ethical Considerations

An ID number was given to each patient participating in the study. No connection was made between the patient and the information gained for the purpose of the research project. Patient IDs, consent forms and research results were kept in a locked cupboard in the research administrator's office.

The Ethics Committee for Human Research at the Sydney Adventist Hospital approved this research project.

3.6 Data collection

Data collection was achieved through the use of the following scales and questionnaires.

3.6.1 RTOG Scoring System For Acute Radiation and Morbidity

The RTOG Scoring System For Acute Radiation and Morbidity (Cox et al, 1995) has been used extensively in empirical studies (Dische, 1994) and is a well-recognised scale for scoring and documenting skin reaction that occurs due to radiation treatments and has well documented Reliability and Validity. A modified version of this scale was utilised in this study, to help differentiate the bright erythema and patchy moist desquamation. Porock and Kristjanson (1999) have used this modification in their studies to give greater differentiation in the scoring of skin reactions.

3.6.2 Visual Analogue Pain Scale

The visual analogue rating scale (VAS) provides a simple way to record subjective estimates of pain intensity. This scale has been used in many areas of health- related research including quality of life instruments (McCormack and Horne, et al, 1988).

The visual analogue pain scale has had its reliability and validity demonstrated. Scott and Huskisson studied the repeatability of the scale. One hundred patients received vertically and horizontally printed scales in a random order. They reported a correlation of 0.99 between the scores. Further testing revealed a correlation of 0.75 between a visual analogue scale printed vertically and a four-point descriptive scale rating pain as slight, moderate, severe, or agonizing (Scott & Huskisson, 1976). Similar analyses have produced correlations ranging from 0.71 to 0.78 between four-point descriptive scales and visual analogue scales printed vertically or horizontally. The visual analogue scale has been described as being well suited to evaluative studies with small sample sizes as it has been found to be more sensitive than verbal rating scales (Sriwatanakul, 1983).

3.6.3 The Radiation-Induced Skin Reaction Assessment Scale

The Radiation-Induced Skin Reaction Assessment Scale developed by Noble-Adams (1999b) has also been used in this study. This scale allows for further assessment of the skin reaction by taking into account not only the skin appearance but also how it actually feels from the patient's point of view. Through clinical appraisal of the scale by experts this scale has a reasonably high inter-rater reliability coefficient (0.07). This scale has not been utilised widely in the field it was designed for.

3.6.4 Demographic Questionnaire (Appendix 4)

A demographic questionnaire was designed to collect personal data and a few short open questions were included to assist in understanding the patient's response to the dressings under trial.

3.6.5 Photographs

Photographs were taken weekly to substantiate the findings throughout the treatment process.

3.7 Analysis

Analysis was carried out through frequencies, comparison of means and other nonparametric tests.

4 Results

4.1 Analysis of Dressing Data

4.1.1 Radiation Induced Skin Reaction Assessment Scores

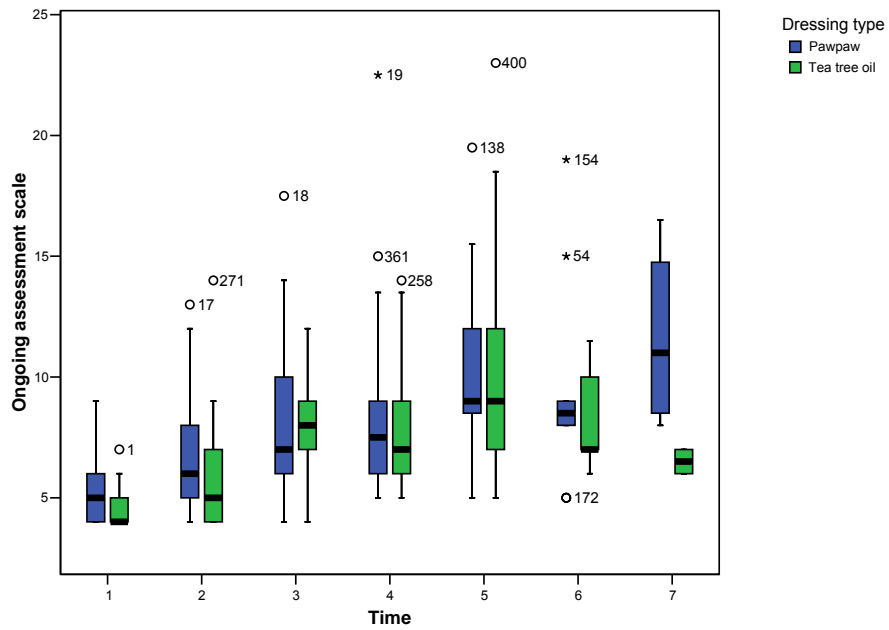
The means, standard errors, and number in each group, of the ongoing assessment variable (RNscr) at times 1,2,...,7 are given in Table 4.1. The p-value is for the hypothesis of no difference in mean assessment between the pawpaw and tea tree oil dressing groups. Using linear regression analyses, corrected for radiation dose, skin type and skin sensitivity, at each time point, (with the exception of time 3), mean assessment for the tea tree oil group is less than (better than) the pawpaw group. However, due to the small sample size these differences did not reach statistical significance.

Table 4.1 Analysis of Nurse Scores for Skin Assessment

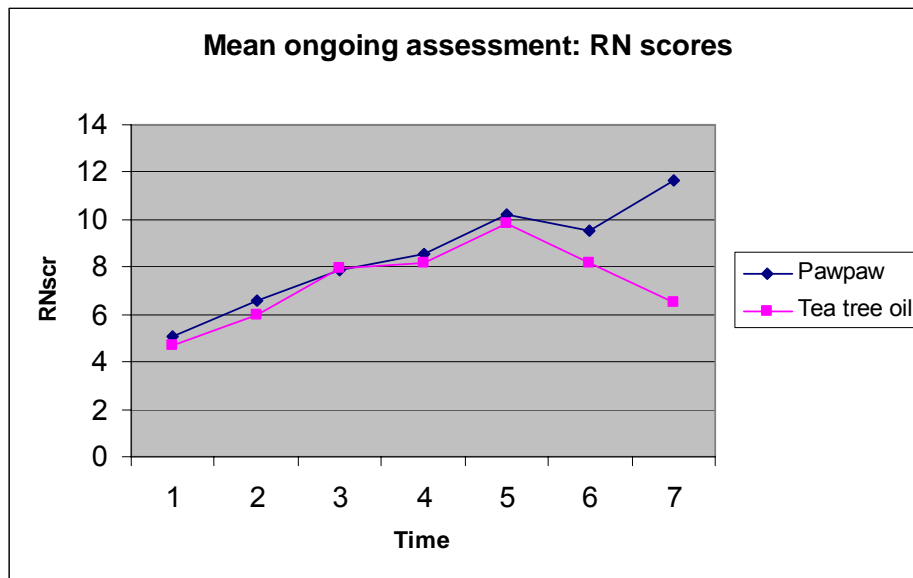
Dressing type		RNscr1	RNscr2	RNscr3	RNscr4	RNscr5	RNscr6	RNscr7
Pawpaw	Mean	5.07	6.62	7.88	8.57	10.21	9.50	11.63
	Std. Error of Mean	0.23	0.48	0.62	0.88	0.87	1.37	1.95
	Number of cases	27	25	25	22	17	10	4
Tea tree oil	Mean	4.70	5.98	7.93	8.14	9.86	8.14	6.50
	Std. Error of Mean	0.18	0.41	0.37	0.51	0.83	0.57	0.50
	Number of cases	27	29	29	28	25	11	2
p-value								
Uncorrected (Two-sample t-test)		0.209	0.314	0.943	0.663	0.781	0.353	0.157
Corrected (Linear regression)		0.671	0.755	0.470	0.620	0.106	0.278	-

The plots below depict the ongoing assessment over time.

Graph 4.1 Nurse Skin Assessment



Graph 4.2 Nurse Skin Assessment Means



Note that at time 7, when there appears to be the greatest difference between the means of the two groups, the number of patients in the pawpaw and tea tree oil groups is 4 and 2, respectively.

4.1.2 RTOG Scores

The following table summarises the doctor scores (Drscr) at times 1, 2, ..., 7:

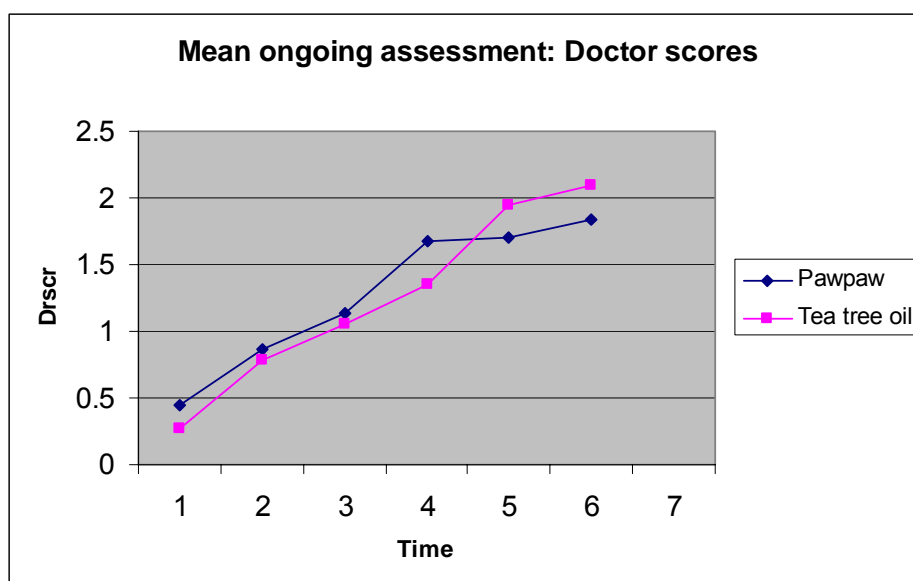
Table 4.2 Analysis of Doctor Scores for Skin Assessment

Dressing type		Drscr1	Drscr2	Drscr3	Drscr4	Drscr5	Drscr6	Drscr7
Pawpaw	Mean	0.45	0.86	1.14	1.68	1.71	1.83	
	Std. Error of Mean	0.15	0.15	0.17	0.14	0.15	0.17	
	Number of cases	21	22	22	22	17	6	
Tea tree oil	Mean	0.27	0.78	1.06	1.35	1.94	2.10	2
	Std. Error of Mean	0.10	0.13	0.11	0.13	0.12	0.07	0
	Number of cases	22	27	26	27	17	10	2
p-value								
Uncorrected (Mann-Whitney U test)		0.404	0.669	0.707	0.105	0.334	0.111	-
Corrected (Ordinal regression)		0.958	0.247	0.952	0.002	0.268	-	-

As doctor scores were in the range 0 to 3, the nonparametric Mann-Whitney U test was used to assess differences at each time point; with ordinal regression. Differences were corrected for radiation dose, skin type and skin sensitivity. Consistent with results observed for nursing scores (Graph 4.2), mean ongoing assessment scores by doctors blinded to the treatment also showed a trend indicating improved outcomes for subjects treated with TTO dressings, resulting in a statistically significant, corrected p-value at week 4. Interestingly doctor scores at times 1, 2, 3 and 4, for tea tree oil are less than those for pawpaw; whereas at times 5 and 6 this is reversed. At time 7 only two observations are available for tea tree oil, and none for pawpaw, so no analysis can be performed at this time.

Boxplots were not constructed for doctor scores, as these were in the range 0 – 3, making the boxplot uninformative.

Graph 4.3 Doctor Skin Assessment Means



5 Discussion of Results

The analysis of the scores from the Radiation Induced Skin Reaction assessment scale (RISRAS) indicated a trend that tea tree oil achieved apparently better results overall than those using the pawpaw ointment, however this was not statistically significant, possibly due to the small sample size. This was confirmed when the RTOG scores showed similar trends for tea tree oil achieving slightly better results than the pawpaw ointment. This is the first time that TTO has been tested in this clinical setting, and the results of the trial suggest that a clinical difference is observed in some patients. This difference was enough to provide comfort to many of those who used it.

It is interesting to note that at assessment points during weeks 5 and 6 this trend reversed. This may suggest that the TTO dressing is less appropriate later in the treatment period however further studies are required to confirm this hypothesis.

In this study the RISRAS was unblinded and utilised by the registered nurses while the RTOG was utilised by the radiation oncologists who were blinded to the dressing being used. It is interesting to note that the RISRAS produced similar results and trends as the well recognised and predominantly used RTOG assessment scale. However the RISRAS provides the health professional with greater understanding of the patient's physical signs and symptoms, which affect their quality of life.

Anecdotally, both products had their positive and negative points. Both products were found by some to be irritating to the skin. TTO was found by some to be offensive in its odour, while pawpaw was found to be thick and greasy, causing staining of clothes requiring a combine dressing to prevent this. The TTO dressing was also difficult to secure, falling off at times, but at other times becoming adherent to the skin producing small skin tears. Positive qualities of both products were their soothing effect on the skin, both products reduced erythema and discomfort and enabled patients to continue with their normal daily activities. TTO dressings had the advantage of a cooling effect on the skin which many patients found beneficial.

6 Implications

Although the sample size was small, the observed trends suggests that the TTO dressing is a product which impacts positively on radiotherapy patients' skin integrity and comfort, and therefore quality of life. Further to this the documented effect of reduction of tissue damage reported by Finlay-Jones and Hart (2001) suggests that perhaps earlier use of this dressing may further reduce the signs and symptoms that we have seen in the study. This was not tested in this study as it was being piloted as an alternative to pawpaw, which is only applied once symptoms appear.

7 Recommendations

The outcomes of this clinical trial, which concentrated on radiotherapy skin reaction only, should now be tested on a larger group with multiple centres involved. This larger trial may provide further evidence of the effectiveness of the Tea Tree Oil dressing in the clinical setting. Further, the trial should be designed in such a way as to determine the appropriate dressing regime for the use of this product. The results of such a study may also lead to Tea Tree Oil hydrogel dressings being suitable in the treatment of other wound types. It would be interesting to compare the application of a TTO product with the application of a product such as aloe vera, which is frequently applied earlier in the course of radiotherapy treatment.

In future studies utilizing these dressings, the protocols must include the need to thoroughly moisten the TTO dressing prior to removal if the patient finds that there is a tendency for the dressing to adhere to the skin.

In response to the comments regarding the odour of the TTO dressing, the manufacturers may need to investigate ways of reducing this concern.

8 Appendices

8.1 Information Letter

Dear Client,

We invite you to participate in a research project being conducted at the Sydney Adventist Hospital and the Sydney Radiotherapy Oncology Centre. This department is committed to give its clients the best health care possible. It is with this goal in mind that a trial of a new dressing is being undertaken. We believe this dressing may be beneficial in the treatment of skin reactions that sometimes result from radiotherapy treatment.

Two dressings with similar properties will be used. Both will provide a similar effect so you will not be disadvantaged with either dressing. The dressing you receive will be selected randomly to provide an unbiased result. The chief investigator for this research is Mr Gary Bain, Clinical Nurse Consultant for Wound Care at Sydney Adventist Hospital and supported by Dr Richard Foster.

If you decide to participate, you will be asked to sign a consent form and complete a short questionnaire about yourself. You will give these to the registered nurse on duty. These will then be collected by myself, Bronwyn Raymond - Research Nurse or Hilary Kuwahata - Project Manager and filed in a secure place. All information will be marked with an identification number. The project manager will keep the only link between your identification and your responses. Be assured that your personal details and responses will be held in the strictest of professional confidence.

The project will require you to have a dressing applied, answer a few questions regarding the effectiveness of the dressing and have some photographs taken of the skin area where the dressing is used during the course of your treatment. Photographs and questions may also be needed as a follow-up after the treatment is completed. If you have any difficulty with the dressings when you are home you may call the registered nurses, Lisa or Paulette, at the Radiation Oncology Centre on 9487-9300 during office hours. The registered nurses may discontinue the trial if they feel a different dressing would be more beneficial, as your treatment progresses.

Please be assured that your radiotherapy treatment will not be altered or affected by this product trial in any way and that you may freely withdraw from the trial at any stage. Your treatment will continue as normal and will not be affected by this decision.

Thank you for considering this research project and we look forward to your participation. If you have any questions about the study please feel free to contact us on 02 9487 9880 during work hours or email hilaryk@sah.org.au. This study has been approved by the Ethics Committee of Sydney Adventist Hospital and if you have questions regarding any ethical issue relating to the study please contact Dr T Ludowici on 9487 9411.

Yours sincerely

For:

Gary Bain, Dr Richard Foster, Hilary Kuwahata, Bronwyn Raymond

8.2 Consent Form

This is a consent form that must be signed to participate in the dressing trial. To participate please print your name and address and sign this form. Thank you for agreeing to be part of this research project.

I, _____ (name)

of _____ (address)

consent to participate in the study being conducted at Sydney Adventist Hospital and Sydney Radiotherapy & Oncology Centre. My involvement in the study has been explained to me. I understand I will fill out a short questionnaire about myself. Also, I will be asked some questions during the course of my treatment about the dressing that is being used. I understand that the dressing I receive will be randomly allocated to me. I also accept that some photographs will be taken of the treatment area, to assist in the assessment of the skin care product.

I understand that any information, that relates to me or my treatment, will be kept in the strictest of confidence. I understand that at anytime I may withdraw from the study without affecting my treatment. If I have any questions I may contact Bronwyn Raymond – Research Nurse on 02 9487 9892, (email: Bronwyn.Raymond@sah.org.au), or Hilary Kuwahata - Project Manager on 02 9487 9880, (email: hilaryk@sah.org.au).

Signature: _____ Date: _____

Witness: _____ Date: _____

Please tick this box if you would like a summary of the findings at the end of this project.

8.3 Skin Care Form

Daily Skin Care

Aim:

To maintain good condition of the skin

Skin Care:

Clean the skin with water being careful not to rub the area being treated. You can use a gentle soap such as Dove soap if you wish.

Apply Cream: We recommended you chose one of these products, Aqueous Hydraderm, Urea Dermadrone Dry Skin Treatment or Vitamin E Cream or oil for use on your skin.

If you use a deodorant it is important you choose one that does not contain aluminium.

Clothing should be loose and not rub on your skin.

If you have any problems please phone 9487-9300 and speak to the registered nurses.

8.4 Demographic Questionnaire



Date ____ / ____ / 2004

Participant ID _____

Dressing Trial Questionnaire .

We would like to ask you a few questions about yourself. Please tick the box next to the answer that relates to you.

Q. 1. Gender Female Male

Q. 2. What is your age? _____ years

Q. 3. Marital status Married Divorced

Defacto Single Widowed

Q.4. Living arrangements

- I live with spouse/ partner/ family/ friend
 I live alone - with someone to call on if I need something (*please specify*) _____
 I live alone - without someone to call on if I need something

Q. 5. Housing arrangements

- Own home Rent home Other (*please specify*) _____

Q. 6. What is the highest level of education you achieved?

- TAFE School Certificate
 HSC University
 Other (*please specify*) _____

Q. 7. How would you describe your economic status?

- Very Good Good Neither good or bad Poor Very Poor

Q. 8 Do you have children under 16 years of age?

- No Yes - *How many* _____

Q. 9. Are you working at present?

- No Yes - *How many hours per week* _____

Q. 10. Do you smoke?

- No Yes - *How many per day* _____

Q. 11. Have you ever had chemotherapy? No Yes

Q. 12. Are you currently on chemotherapy? No Yes

Nursing Staff to complete this section.

Date ____ / ____ / 2004 Week of Treatment _____ Participant ID _____

Inpatient Outpatient

Q. 24. Does the patient have any Allergies? (please note natural plant products)

No Yes (please specify) _____

Q. 25. Patient weight _____ kgs

Q. 26. Fill out the FBBC malnutrition screening tool© below

<p>* Have you lost weight recently without trying? If no If unsure</p>	<p>0 2</p>
<p>* If yes, how much weight (kg) have you lost? 0.5 –5.0 kg >5.0 – 10.0 kg >10.0 – 15.0 kg >15.0kg Unsure</p>	<p>1 2 3 4 2</p>
<p>* Have you eaten poorly because of a decreased appetite? No Yes</p>	<p>1 2</p>

Total: _____

If the score is 3 or more, please refer to dietician.

(FBBC malnutrition screening tool, Copyright © 1996 FBBC Nutrition Research Group. Reproduced with permission of the FBBC Nutrition Research Group.)

Q 27. Health Care Professional Scale

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 (>75-100%)
Moist desquamation(MD)	0 (normal skin)	1.5 (<25%)	3 (<25-50%)	4.5 (>50-75%)	6.0 (>75-100%)
Necrosis (N)	0 (normal skin)	2.5 (<25%)	5 (<25-50%)	7.5 (>50-75%)	10 (>75-100%)

Ongoing assessment scale

Date	No.	E	DD	MD	N	Pain	Itch	Burn	Activities	Total

Please note Treatment and Creams being used.

Aqueous Hydraderm Or Urea Dermadrate Dry Skin Treatment
 Or Vitamine E cream Date ____ / ____ 2004

Dressing applied A or B Date ____ / ____ 2004

Photograph taken Yes or No Date ____ / ____ 2004, Time _____

Other Comments:

Please note any medications patient is on.

Medical Officer to complete this section.

Participant ID _____

Q. 28. Radiation Dose

Treatment start date: _____

Treatment finish date: _____

Number of days on treatment: _____

	Phase 1	Phase 2	Phase 3
Dose per fraction (cGy)			
Total no. of fractions			
Total dose per phase (cGy).			
Radiation Type (e.g. photons, 12 MeV electrons).			

Overall maximum dose in PTV (cGy): _____

Overall minimum dose in PTV (cGy): _____

Q. 29. Radiation Site

Head and Neck

Breast / chest

Skin

Q. 30. RTOG Acute radiation scoring criteria – skin

0	1	2	2.5	3	4
No change Over baseline	Follicular, faint or dull erythema; epilation; dry desquamation; decreased sweating	Tender or bright erythema	Tender or bright erythema, patchy moist desquamation; moderate oedema	Confluent, moist desquamation other than skinfolds, pitting oedema	Ulceration, Haemorrhage or necrosis

Review	Review Date	Skin Score	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

8.5 Weekly Assessment Questionnaire



____ / ____ / 2004

Participant ID _____

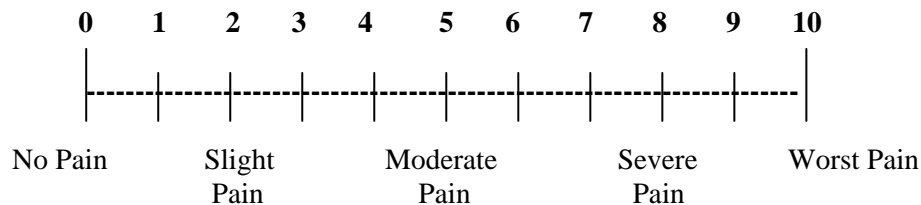
Dressing Trial Study Weekly Visits Assessment Questionnaire

The following questions relate to your skin

Please circle the number that describes your skin in area being treated.

Symptoms	Not at all	A little	Quite a bit	Very much
Q. 1. Do you have any tenderness, discomfort or pain of your skin ?	1	2	3	4
Q. 2. Does your skin itch?	1	2	3	4
Q. 3. Do you have a burning sensation of your skin ?	1	2	3	4
Q. 4. To what extent has your skin reaction and your symptoms affected your day-to-day activities?	1	2	3	4

Q. 5. On a scale of zero to ten how would you rate the skin pain you are experiencing (0 being no pain at all and 10 being the worst pain you could imagine)? **Mark your answer on the line below.**

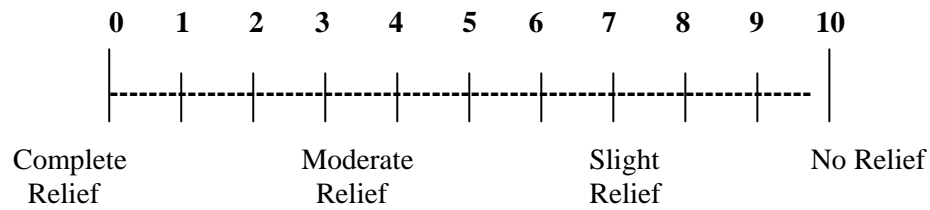


Q. 6. Have you been able to follow the skin care advice given to you by the staff?

Yes No In part please explain _____

If you have experienced any symptoms please answer the following questions. If you have not have any symptoms thank you for your time today.

Q. 7. Now that your dressing has been done please rate on a scale of zero to ten the relief from pain you are now experiencing (0 being complete relief from pain & 10 being no relief from pain)? **Mark your answer on the line below.**



Symptoms	Instantly	After 5 minutes	After 10 minutes	Not relieved	N/A
Q.8. If you experienced tenderness, discomfort or pain of your skin how soon after the dressing was applied was this relieved?	1	2	3	4	5
Q. 9. If you experienced an itching sensation of your skin how soon after the dressing was applied was this relieved?	1	2	3	4	5
Q. 10. If you experienced a burning sensation of you skin how soon after the dressing was applied was this relieved?	1	2	3	4	5

Q. 11. Was the dressing comfortable?
 Yes No *please explain* _____

Q. 12. Was the dressing easy to apply?
 Yes No *please explain* _____

Q.13. Did you experience any difficulties with the dressing other than those already mentioned?
 Yes No
If yes please tell what you experienced?

Thank you for answering this questionnaire.

Nursing Staff to complete this section.

Date ____ / ____ / 2004 Week of Treatment _____ Participant ID _____

Q. 14. Has the patient had any reaction to the dressing? (please note natural plant products)

No Yes (please specify) _____

Q 15. Health Care Professional Scale

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 (>75-100%)
Moist desquamation (MD)	0 (normal skin)	1.5 (<25%)	3 (<25-50%)	4.5 (>50-75%)	6.0 (>75-100%)
Necrosis (N)	0 (normal skin)	2.5 (<25%)	5 (<25-50%)	7.5 (>50-75%)	10 (>75-100%)

Ongoing assessment scale

Date	No.	E	DD	MD	N	Pain	Itch	Burn	Activities	Total	
Please note Treatment and Creams being used.											
Aqueous Hydraderm		<input type="checkbox"/>	or		Urea Dermadrane Dry Skin Treatment		<input type="checkbox"/>				
Or Vitamine E cream		<input type="checkbox"/>	Date ____ / ____ 2004								
Dressing applied		<input type="checkbox"/>	A		or		<input type="checkbox"/>	B		Date ____ / ____ 2004	
Photograph taken		<input type="checkbox"/>	Yes		or		<input type="checkbox"/>	No		Date ____ / ____ 2004, Time ____	
Other Comments:											

Please continue over page.

Q. 16. Patient weight _____ kgs

Q. 17. Fill out the FBBC malnutrition screening tool© below

Have you lost weight recently without trying?	
If no	0
If unsure	2
If yes, how much weight (kg) have you lost?	
0.5 –5.0 kg	1
>5.0 – 10.0 kg	2
>10.0 – 15.0 kg	3
>15.0kg	4
Unsure	2
Have you eaten poorly because of a decreased appetite?	
No	1
Yes	2

Total: _____

If the score is 3 or more, please refer to dietician.

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8.6 Decision Making Protocol

When to treat skin irritation in Radiotherapy patients

When considering to treat a patient's skin irritation brought about by radiation therapy two main things must be considered - firstly the patient's perception of pain and irritation and secondly the physical signs that are present at the time of skin examination.

The Sydney Radiation and Oncology Centre employ two experienced registered nurses. These Registered nurses were primarily involved in the clinical assessment of the skin and decision-making on when to commence the dressing regime assigned to that patient.

The registered nurses decision to commence dressings to the treatment area was based on the following information, which they gained through talking to the patient and observing the treatment area. "It's all about the way it feels" commented one RN, The patients perception of pain and irritation must be taken into account. Symptoms of itching, burning and pain that affect the patients feeling of well-being must be taken into account. This information, coupled with the physical signs observed when examining the skin, of pinkish red to dull red (scoring 1-2 on the ... scale) indicate when treatment should commence. "You can't ignore what they're telling you". Sometimes the decision was made to apply a dressing to the treatment area based on only signs or symptoms alone for example the skin was a bright red but the patient did not indicate that they were experiencing any symptoms. The patients were often unsure of how they felt due to the fact that they did not know how they were meant to feel, so had nothing to measure against. This was where the scale was felt to be useful in the decision making process.

Patient history of sensitive skin was also taken into account when carrying out examinations as understanding the patients concerns helped in providing support and appropriate treatment. This in turn made them feel more confident in their treatment.

Some patients had a preference for a product due to a friend or relative recommending it.

9 Glossary

Erythema:

Redness of the skin produced by congestion of the capillaries, which may result from a variety of causes.

Dry desquamation:

The shedding of epidermal skin but the skin surface remains dry. The patient often experiences dry flaking skin associated with tenderness and itching. Dry desquamation indicates that the basal layer has repaired itself prior to epidermal shedding (Sitton, 1992; Noble-Adams, 1999).

Moist desquamation:

The dermis is exposed because the basal layer has not completed itself prior to skin shedding. At this stage the skin is moist with serum. The risk of infection is increased as is the pain and burning sensation experienced by the patient (Noble-Adams, 1999). Continued irradiation or an opportunistic infection can lead to extensive dermal damage or even necrosis. Approximately, 10-15% of patients succumb to moist desquamation (Blackmar, 1997; Porock & Kristjanson, 1999; Sitton, 1992; Wells & MacBride, 2003).

Necrosis:

The sum of the morphological changes indicative of cell death and caused by the progressive degradative action of enzymes, it may affect groups of cells or part of a structure or an organ.

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