



# **Non-contact low-frequency ultrasound (NCLF) to improve dermatitis, pain, & quality of life after radiation therapy: The Soothe Study**

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A large, detailed microscopic image of numerous small, spherical bubbles or droplets, likely water or a similar liquid, arranged in a dense, somewhat circular pattern. The bubbles vary in size and are set against a light, textured background.

# Background

- ❖ Breast cancer is the second leading cause of death in US women
- ❖ Different types of treatment methods including surgery, chemotherapy and radiation therapy have been used to eradicate this tumor

# Background cont.

- ❖ The benefit of radiation therapy after removing the tumor is the reduction in recurrence.
- ❖ Radiation therapy might be able to save lives, but can cause debilitating dermatitis.

# Pathophysiology

- ❖ Radiation dermatitis is one of the most remarkable reactions that not only effects quality of life but can also interfere with treatment and even result in termination of therapy.
- ❖ Radiation dermatitis occurs when “high-energy X-ray is delivered” during the treatment and lead to “direct and indirect macro-molecules” causing dsDNA breaks. This breaks the cells in the dermis and epidermis causing irritation to the skin layer

# Radiation dermatitis



*Grade 2 radiation dermatitis following external radiotherapy for breast cancer*



*Grade 3 radiation dermatitis following external radiotherapy for breast cancer*

# Treatment

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# Standard of care

- ❖ Standard of care treatment is using silver-based creams to the effected side to help with the healing process.
- ❖ However, this takes weeks to heal and leads to a great deal of pain and risk of infection.

# Non-contrast low frequency ultrasound (NCLF)

- ❖ This device has been developed and does not require use of a coupling gel or other direct contact.
- ❖ Also known as: MIST therapy
- ❖ It promotes wound healing through wound cleansing and maintenance debridement by removing yellow slough, fibrin, tissue exudates and bacteria

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# Non-contrast low frequency ultrasound

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# Non-contrast low frequency ultrasound

- ❖ Delivers saline mist to the wound with low frequency ultrasound (40kHz)
- ❖ The device is held 0.5 to 1.5cm from the wound and saline is delivered to the wound bed
  - This promotes healing through stimulation of cellular activity
- ❖ Each session usually lasts 10-15 minutes

# NCLF therapy benefits

- ❖ In one study NCLF was used in non-healing diabetic leg ulcers and showed significant clinical improvement
- ❖ It decreased pain, bacterial count and inflammatory cytokine levels

# Gap in the literature

- ❖ Non-contrast low frequency ultrasound has shown to improve wounds in many situations, but has not yet been studied in radiation dermatitis

# Aim of the study

- ❖ The aim of this study is to determine if NCLF will reduce the days of grade 2 or above dermatitis when compared to standard of care in patients with post breast cancer radiation therapy.

# Method

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# Inclusion Criteria

## **Participants included in the study**

- ❖ Women 18 years or older with breast cancer s/p radiation
- ❖ Grade 2 or higher radiation dermatitis

# Exclusion Criteria

## **Participants that were excluded**

- ❖ Patients with evidence of residual disease
- ❖ Unable to follow treatment regimen
- ❖ Inflammatory breast cancer disease
- ❖ Positive margin at resection
- ❖ Allergy to sulfa medications
- ❖ Presence of pacemaker or any other electronic devices

# Methods cont.

- ❖ Approximately 63 subjects with diagnosed breast cancer were referred and recruited from the St. Joseph's Cancer Center the day of completion of their radiation course of treatment from Dr Singh's practice.
- ❖ Once consent to participate was obtained, patients were randomized to receive either St. Joseph's Medical Center standard of care treatment or NCLF therapy AND standard of care treatment.

## Methods cont.

- ❖ Patients who had multiple sites with grade 2 dermatitis or above, only one site with the highest level was studied
- ❖ Since skin fold areas have higher friction and longer healing time associated with them, these areas alone were used for this study

# SCHEMA

Day	Consent	Pain Survey	Dermatitis Scoring	QOL survey	Photograph	Treatment
1	X	X	X	X	X	X
2		X	X		X	X
3		X	X		X	X
4+		X	X		X	X
Final treatment		X	X		X	X
Post treatment F/U		X	X	X	X	

## Methods cont.

- ❖ Number of treatment days varied but were continued daily until dermatitis score was a grade 1 for both groups
- ❖ On weekends patients were educated on wound care regimen
- ❖ Treatment group who received NCLF US utilized the MIST system manufactured by Alliqua Biomedical, plus standardized wound regimen (Silvadene cream)
- ❖ Post treatment follow up in 3-5 days s/p final treatment day

# Results

- ❖ Sixty-three (63) female patients were enrolled; mean age 56 years.
  - On average, patients in the treatment group (SOC plus NCLF) took less time to resolve to a grade 1 dermatitis (*Mean* = 7.77 days, *SE* = 0.569), than those who received SOC alone (*Mean* = 10.52 days, *SE* = 0.698)
- ❖ This difference was clinically and statistically significant at 2.75 days ( $t = 3.053, p=0.0017$ )
- ❖ The treatment group had an improvement in their Quality of Life score utilizing a validated instrument (FACT-G7) than those who received SOC alone; however this was not statistically significant

# Results cont.



# Conclusion

- ❖ This study showed that NCLF ultrasound reduces healing time of grade 2 or above radiation dermatitis in women treated for breast cancer compared to standard of care alone.



# Limitations

- ❖ Small sample, one center, but overall promising results



**Thank you**



**Any Questions?**