

A Pilot Study Evaluating Skin Toxicity in Radiation Treated Breast Cancer Patients Using RadiaPlexRx™ Topical Gel Containing 0.2% Hyaluronic Acid, Allantoin, and Aloe vera Extract

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An estimated 90% of breast cancer patients treated with radiotherapy will develop radiation dermatitis (Harper, 2004). Therapeutic doses of radiation cause persistent skin erythema, desquamation, rash, pain, itching and ulceration increasing risk of infection. Some clinicians suggest radiodermatitis be treated for the life of the patient because of collateral skin damage. Chemotherapy increases significantly the severity of acute radioepithelitis (Liguori, 1997). Skin toxicity results of 108 irradiated breast cancer patients who underwent mastectomy, breast cancer preserving therapy, and some with adjuvant chemotherapy found 92% erythema, 30% dry desquamation, 35% moist desquamation, and 14% ulceration (Lopez, 2002).

Presently in the U.S., U.K., and Europe there is no evidence based optimal treatment for radiation dermatitis (Wickline, 2004). Clinics showed a variety of treatments for radiodermatitis, many of which have no scientific bases. Typical products contain oil, water, and lanolin but may not contain ingredients evaluated for efficacy towards skin protection.

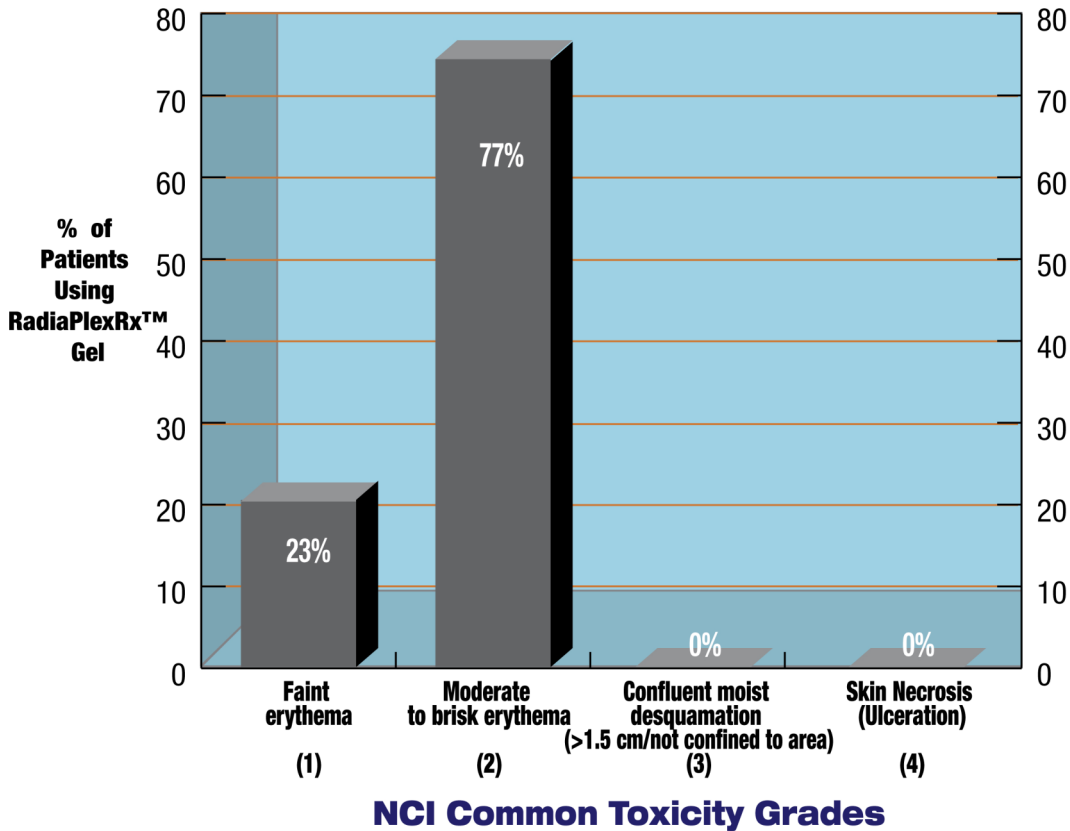
A topical gel, RadiaPlexRX® (RPX), was formulated containing 0.2% hyaluronic acid (HA) and active polysaccharide extract from aloe vera. HA is the main constituent and the main water holding molecule of the dermal matrix. The HA-fibrin matrix organizes a three dimensional matrix for tissue reconstruction, to stimulate wound healing and to resist bacterial infections (Weigel, 1986). When RPX gel was incubated with human fibroblasts, cells were protected against oxidative and ionizing X-ray damage (20% and 30% less cell

death, respectively) (Gracy, 2004). A 0.2% HA formula was shown clinically (n=134) to significantly reduce early and late acute symptoms of radiodermatitis against placebo (Liguori, 1997).

An ongoing pilot study was undertaken to evaluate RPX gel for quality of life criteria for patients applying the gel during breast irradiation treatment following lumpectomy. Patients (n=13) undergoing radiation (median 6040 cGy) after breast surgery were instructed to apply a thin layer of gel to the irradiated area 3 times daily after washing skin with soap and water. Oncology nurses scored skin appearance for 6 ½ weeks during treatment. Patients were given a questionnaire developed by nurse oncologists to evaluate gel characteristics during application to irradiated breast including pain, itching, ease of use, moisturizing effects, etc. Nurses' scoring and patients' responses were evaluated using SPSS.

The NCI acute skin toxicity analyses showed that 23% of the breast patients experienced faint erythema (grade 1) and 77% experienced moderate to brisk erythema (grade 2). There were no grade 3, confluent moist desquamations, or ulcerations observed in the group evaluated thus far. No dry desquamation was observed in 85% of patients and was limited in remaining patients.

Breast Radiation Patients Using RadiaPlex Showed No Grade 3 or 4 Skin Toxicity



Patient responses showed 77% applied gel three times daily, others twice daily. Patient responses showed 85% did not develop itching and 69% reported no painful skin problems during treatment. No rash occurred in 84% of patients under the treated breast or breast fold. Considering unique sensitivity of breast skin during radiation, observations indicate a high tolerance of the gel by patients. Overall patient evaluations showed support for quality of life, comfort, and usability (100% would recommend gel to others). Lack of confluent moist desquamation indicated preservation of skin integrity supporting prior published works on ingredient effectiveness. Results support use of the gel and studies are warranted to compare outcomes with other products or to conditions of no treatment.

References

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